A. ...The reimbursement with our provider groups, when negotiating, is considered in total, so it's the final total contract that may be decided–that will be decided upon, and there are trade-offs made between the different services as you go through the process of negotiation and compromise to get to a solution that is agreeable to both parties...

Q. So could there ever be a case where Cigna may agree to a higher reimbursement for the–for injectable drugs, for example, and–in exchange for a lower reimbursement for the physician's administrative fee?...

A. That could be a potential trade-off that does happen during the negotiation process.[209]

- Mike Beaderstadt, Director of Provider Relations at John Deere Health, states:

  Q. Was any consideration given to having an additional carve-out, for example, for oncology drugs.

  A. What we attempted to do, in most cases we're successful, is when the oncologist complained about the reimbursement, rather than changing the reimbursement for the drug itself, we changed the reimbursement for the administration of that drug, which is a separate CPT code.[210]

- An internal John Deere Health document demonstrates that increases in service payments may subsidize the drug reimbursement transition from 110 percent of AWP to 87 percent of AWP:

  There may be a way to cushion the blow of a change in fee schedule by adjusting the conversion factor for office visits. This will offset the change in payment to some extent.

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[209] Herbold deposition, pp. 61–62.
[210] Beaderstadt deposition p. 60.

Response: The Midwest is considering increasing fees to the oncologists for chemotherapy admin codes to partially offset the lost revenue from the J-codes. The Southeast has no specific plans for offsetting the J-code revenue loss for physicians, but will develop strategies to retain providers as circumstances dictate.[211]

- Joseph Spahn, Senior Health Care Consultant for Anthem Midwest, states:

  Q. Okay. So the recommendation that you made was that if they were to lower, or if the amounts that they reimbursed in relation to drugs were to fall, then they would need to correspondingly increase the administration fee?

  A. Correct.[212]

(91)   Dr. Hartman inappropriately dismisses these interdependencies because he incorrectly asserts that if cost signals underlying the reimbursement for the bundle are incorrect, "the total reimbursement rate allowed for the medical benefit will be incorrect."[213] As I noted in Section III.3, this assertion assumes, contrary to the evidence, that TPPs believed that AWP was a reliable signal for provider acquisition costs. More importantly, as shown below, the assertion is demonstrably false in light of the evidence that TPPs explicitly raised their payments for physician services to offset reductions in drug reimbursements when switching to an ASP-based methodology.

(92)   For example, claim data from Health Net California ("Health Net") demonstrate that physician service fees increased as Health Net transitioned to an ASP-based methodology in January 2004.[214] Health Net's reimbursements for doxorubicin (J9000)[215] decreased from $42.50 in fourth quarter 2003 to $8.97 in second quarter 2004. Over the same time period,

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[211]   JDH 000287.

[212]   Spahn deposition, p. 115.

[213]   Hartman Liability and Damages Declaration, Attachment K, p. 8. Dr. Hartman also relies on understanding from counsel that "the fact that a fraud is committed to subsidize other activities does not immunize it from legal scrutiny." I will not comment on legal questions.

[214]   Deposition of Karla Austen of Health Net ("Austen deposition"), p. 57.

[215]   Bristol-Myers Squibb's Rubex is the brand-name version of doxorubicin.

Declaration of Eric M. Gaier, Ph.D.   Drugs reimbursed by TPPs outside the Medicare context

however, Health Net's reimbursements for service 90780, commonly associated with administration of doxorubicin, increased from $53.76 to over $86.77. These countervailing changes for Health Net are shown in Figure 7.[216]

Figure 7: Health Net median reimbursements for drug J9000 (doxorubicin) and most often associated service 90780 (IV infusion therapy, 1 hour)
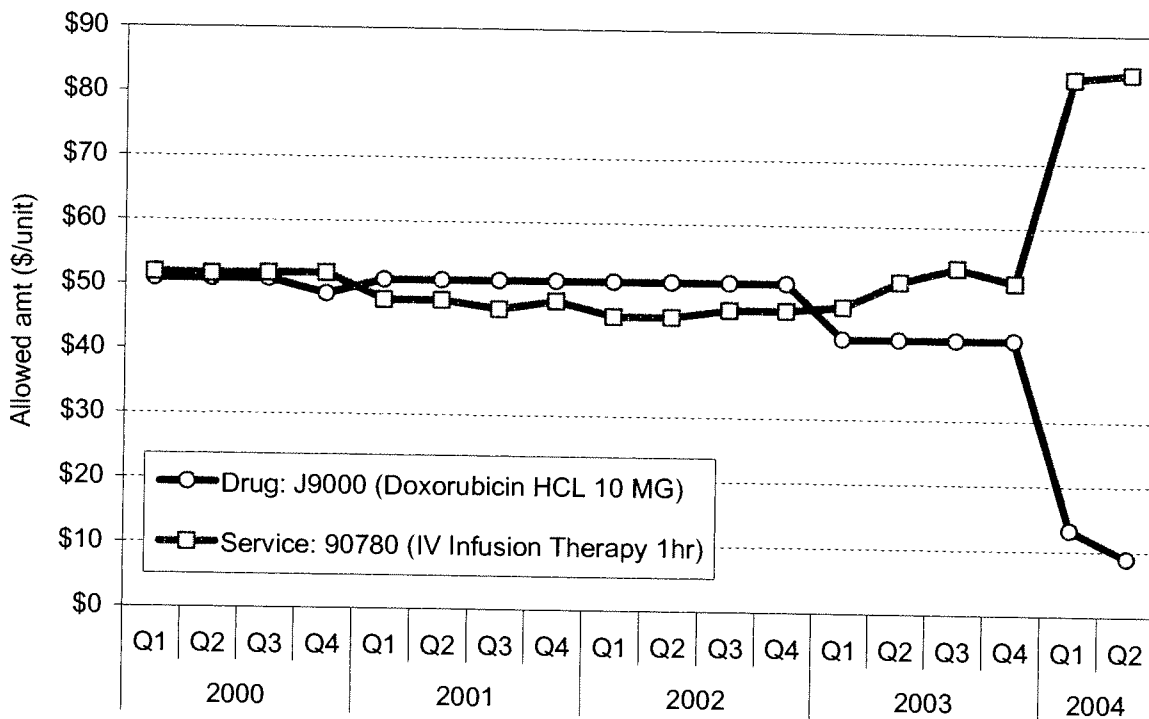
Source: Health Net California claim data.

(93)   Interdependencies also exist between drugs reimbursed under the same provider contract. For example, I note the following excerpt from the Trigon document introduced above:

> Trigon recognizes that your acquisition cost for drugs is highly variable when expressed as a percent of the AWP. Ninety percent of AWP should provide

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[216]   See Appendix D for a discussion of the electronic data sources and procedures used to generate this figure.

you with substantial margins for some drugs and nearly zero margins for others.[217]

Therefore, analyzing reimbursements for individual drugs in isolation from other drugs is also not sufficient for a determination of economic harm.

(94)   The evidence demonstrates that TPP drug reimbursements have historically subsidized underpayment for physician services. This cross subsidy creates interdependency between payments for drugs and services, which precludes a determination of economic harm by analyzing drug reimbursements in isolation. Since Dr. Hartman's analysis fails to account for this interdependency, I conclude that his yardstick methodology is unreliable and overstates the purported damages he calculates.

IV.4. Numerous smaller payors benefited from the knowledge, sophistication, and competitive leverage of the larger TPPs

(95)   Numerous smaller payors also would not have overpaid for physician-administered drugs as a result of the alleged AWP scheme because they contract with large and sophisticated TPPs. For example, Plaintiff BCBS-MA and other large Massachusetts TPPs administer the health benefit for numerous union trust funds and other smaller payors:

- Plaintiff Pipefitters Local #537 utilizes the BCBS-MA provider network and pays the allowed charges agreed to between BCBS-MA and the network providers.[218]

- Teamsters Local 170 Health & Welfare Fund contracts with plaintiff BCBS-MA. Beneficiaries can choose between Network Blue New England and Fallon Community Health Plan.[219]

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[217] A-VA 03010065-A-VA 03010068.

[218] Deposition of Denise DeMaina of BCBS-MA, p. 83. Also see BCBSMA-AWP-11996.

[219] http://www.teamsters170hwf.com/health/hp_index.asp. Teamsters also has a separate administrator for prescription drug benefits: "Your Prescription Drug Benefit Program under The Teamsters Local 170 Health & Welfare Fund prescription drug program is administered by Medcohealth Solutions Inc.,

- Teamsters Local 25 Health & Welfare Fund contracts with plaintiff BCBS-MA and Tufts.[220] Beneficiaries can choose either the Network Blue New England or the Tufts EPO, both of which are HMOs formed by the TPP and not the union.[221]

- Plumbers and Pipefitters' Union Local 4 contracts with the following large TPPs (plans noted in parentheses): BCBS-MA (Managed Blue and Medex 3), Fallon (Senior, Direct, Select), and Harvard Pilgrim (PPO).[222] The provider networks in each of these plans appear to be formed by the TPP, not the union.[223]

Under these arrangements, smaller payors generally utilize the provider networks and negotiated reimbursement rates of the larger, more sophisticated TPPs. Steve Fox, Senior Director of Provider Relations, Communications, and eHealth at BCBS-MA states:

> Q. Are you aware of any employer plans in Massachusetts including unions' health and welfare funds that maintain their own provider networks?
>
> A. I'm not aware of any that maintain their own.
>
> Q. Are you aware of any employer plans—including health and welfare funds—that negotiate reimbursement rates with physicians directly?
>
> A. I'm not aware of that.[224]

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administrator of the retail pharmacy program, and Merck-Medco Rx Services, provider of the mail service pharmacy program." See http://www.teamsters170hwf.com/health/hp_rx_benefit.asp.

[220] http://www.teamsterscare.com/benefits.html.

[221] http://www.teamsterscare.com/providers.html.

[222] http://www.ualocal4.org/Health%20&%20Welfare.htm.

[223] BCBS-MA's Managed Blue plan uses its Massachusetts HMO Blue Network. BCBS-MA's Medex 3 plan includes all Medicare-eligible providers; See http://www.brokercentral.bcbsma.com/bcbsma/Materials.nsf/pdfs/Managed%20Blue%20without%20formulary_012005.html/$File/BQ_53734B_MB_SR_WOF.pdf?OpenElement&iphl=managing:manages:managed:manage:blues:blue: and http://www.brokercentral.bcbsma.com/bcbsma/Materials.nsf/pdfs/Medex%203_010104.html/$File/BQ_42459B_Medex_3.pdf?OpenElement&iphl=medex:3:. Except in urgent care situations, all enrollees in Fallon's Senior plan must use a Fallon Senior Plan Preferred network provider; Fallon's Direct plan includes 330 physicians with Acton Medical Associates, Charles River Medical Associates, Fallon Clinic, and Southboro Medical Group; Fallon's Select plan uses the FCHP Select Care network; See http://www.fchp.org/plans/DesignOptions.aspx and http://www.fchp.org/SeniorPortal/About/Index.aspx.; Harvard Pilgrim's PPO plan uses its own participating provider network. See http://www.harvardpilgrim.org/portal/page?_pageid=213,54548&_dad=portal&_schema=PORTAL.

[224] Fox deposition, pp. 224–225.

Because small payors employ the reimbursement rates negotiated by large TPPs, I conclude that numerous smaller TPPs also would not have suffered economic harm from the alleged AWP scheme.

IV.5. Conclusion

(96)   On the basis of TPP knowledge and sophistication, competitive leverage, and use of drug reimbursements to subsidize underpayment for physician services, I conclude that numerous TPPs would not have overpaid for physician-administered drugs as a result of the alleged AWP scheme and would not have suffered economic harm. It therefore follows that those beneficiaries that make coinsurance payments under coverage from these TPPs also would not have suffered economic harm as a result of the alleged AWP scheme. Moreover, none of the evidence I have reviewed leads me to conclude that any TPP would have overpaid for physician-administered drugs as a result of the alleged AWP scheme.

Declaration of Eric M. Gaier, Ph.D.

V. Dr. Hartman's yardstick methodology is unreliable

In this section I, discuss four fundamental flaws in Dr. Hartman's yardstick methodology:

- Dr. Hartman's yardstick methodology is unscientific and unreliable because it cannot distinguish the alleged scheme from economic factors, including those discussed by Dr. Berndt, that provide manufacturers with legitimate incentives to maintain and raise AWPs (or WACs) and lead to legitimate differences between AWP and ASP. Indeed, the pricing patterns that plaintiffs' experts Drs. Hartman and Rosenthal assert result from the alleged AWP scheme are consistent with well-known features of legitimate price competition in many markets, including pharmaceutical markets. Therefore, Dr. Hartman's yardstick methodology amounts to an assumption that the observed patterns are the result of the alleged AWP scheme. Moreover, Dr. Hartman's use of yardsticks based upon SSIDs facing no therapeutic competition to draw conclusions about drugs facing therapeutic and generic competition is inappropriate because it confounds the purported effects of the alleged AWP scheme with legitimate competitive pricing factors.

- Dr. Hartman's yardstick methodology is inappropriate because it is premised on an incorrect assumption that TPPs expected AWP to have a reasonably predictable relationship to acquisition costs. As discussed in Section IV.1, the evidence demonstrates that numerous TPPs did not believe that AWP was a reliable signal for acquisition costs. Thus, Dr. Hartman's expectation approach is not appropriate.

- It is possible to demonstrate the arbitrary and unreliable nature of Dr. Hartman's average expectation approach by applying his methodology using yardsticks that reflect the information available to payors during the class period. For example, I use the information from the 1992 and 1997 OIG reports, as well as information available to TPPs through their direct purchases of physician-administered drugs to construct alternative yardsticks. Doing so, I reduce the purported damages Dr. Hartman calculates by 40 to 99 percent for Classes 1 and 2 and by 27 to 99 percent for Class 3. I therefore conclude that Dr. Hartman's yardstick methodology is arbitrary, unreliable, and overstates the purported damages he calculates.

- Contrary to Dr. Hartman's flawed analysis of a single payor, a more thorough review of the available evidence demonstrates that a significant portion of reimbursements would not have been based upon AWP as a pricing standard. Dr. Hartman's failure to identify and exclude reimbursements not based upon AWP as a pricing standard renders his

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methodology unreliable and causes him to overstate the purported damages he calculates by an amount unknowable without substantial individualized inquiry.

V.1. Dr. Hartman ignores well-known and legitimate economic factors

(97)   In his December 15, 2005 Declaration, Dr. Hartman asserts a liability yardstick of 30 percent for the difference between AWP and ASP, expressed as a markup over ASP.[225] Thus, Dr. Hartman concludes that defendant manufacturers fraudulently inflated the "spread" whenever the actual difference between AWP and ASP exceeds 30 percent, which he examines for each subject NDC on an annual basis. Dr. Hartman purportedly derives the 30 percent yardstick from analyzing SSIDs that face no therapeutic competition. I discuss the appropriateness of Dr. Hartman's use of these SSIDs later in this section.

(98)   With respect to non-Medicare reimbursements under Class 3, Dr. Hartman calculates damages as the difference between the actual "spread" and the 30 percent yardstick. Thus, any increase in "spread" above 30 percent contributes to Dr. Hartman's purported damages for Class 3. However, with respect to Medicare reimbursements from 1991 to 2003 under Classes 1 and 2, Dr. Hartman calculates damages as the difference between the actual "spread" and a zero percent yardstick. Thus, any difference between AWP and ASP contributes to Dr. Hartman's purported Classes 1 and 2 damages, so long as the 30 percent liability threshold has been exceeded.[226] Dr. Hartman purports to justify the zero percent damage yardstick for Medicare reimbursements with reference to regulation. However, as I discussed in Section III.1, Dr. Hartman ignores substantial evidence that Medicare knew AWP did not equal and was not a reliable proxy for EAC, and did not pursue an EAC-based reimbursement methodology.

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[225] Hartman Liability and Damages Declaration, p. 40.

[226] The 30 percent liability threshold is applied in Dr. Hartman's December 15 Liability and Damages Declaration. In his February 3 Addendum, Dr. Hartman reduces this liability threshold to zero for Classes 1 and 2.

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(99)   In his February 3, 2006 Addendum, Dr. Hartman offers alternative damage calculations for Class I and II based upon a zero percent liability yardstick from 1991 to 2003. Under these calculations, Dr. Hartman concludes that defendant manufacturers are liable with respect to Medicare reimbursements for any difference between AWP and ASP. I note that, in conjunction with changes in his calculation of ASPs, the change in liability yardstick increases the purported damages Dr. Hartman calculates for Classes 1 and 2 by 44 percent.[227] This demonstrates that a substantial number of subject NDCs have "spreads" between zero and 30 percent.

(100)   In discussing Dr. Hartman's yardstick methodology, Dr. Berndt highlights a variety of legitimate economic factors, unrelated to the alleged AWP scheme, that affect manufacturers' pricing incentives.[228] According to Dr. Berndt, these factors include:

- "therapeutic class"

- "side effect, efficacy and convenience profiles relative to competitors in the class"

- "number of single-source brand name competitors in the same therapeutic class"

- "class of trade purchaser"

- "whether any brands in the same therapeutic class are multisource, i.e. have generic competitors"

- "time before expected patent expiration and initial generic entry."[229]

(101)   Dr. Berndt then states the primary challenge facing plaintiffs' expert:

> How can it be determined that at any given point in time, it is one or more of the above factors that affected and were largely responsible for the price

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[227]   In his February 3 Addendum, Dr. Hartman calculates an ASP that he admits is inconsistent with his characterization of Medicare regulation. He states that in his original report, "…I used the ASPs of [non-hospital physician] providers, because certainly the Medicare statutes describe reimbursements in terms of the acquisition cost of providers or the average sales prices to providers…" He further states, "The ASP that is used in the supplemental report is a broader definition of acquisition costs than are found in Medicare." See Hartman deposition, Volume III, pp. 656–661.

[228]   Although Dr. Berndt mentioned these factors in the context of self-administered drugs, they are also relevant for physician-administered drugs.

[229]   Berndt Report, p. 115.

decisions made by defendant manufacturers during the product's life cycle, rather than the Defendants' alleged AWP scheme to collect inflated prescription drug payments? Simply examining and recording larger differences in percent 'spreads' between each AWPID drug and 'drugs not subject to this Litigation' will not be sufficient to establish reliably that any differential 'spread' is attributable solely, partly, or not at all to the alleged AWP scheme to collect inflated prescription drug payments.[230]

Yet, simply examining and recording larger differences in percent "spreads" is all that Dr. Hartman has done.[231] Dr. Berndt discusses several potential methodologies, including regression analysis, but Dr. Hartman has not undertaken any of them.[232] As I discuss below, the observed AWP and ASP patterns are consistent with well-known features of price competition in many markets, including pharmaceutical markets. Therefore, Dr. Hartman's failure to consider and distinguish the effects of legitimate economic pricing factors amounts to an assumption that observed patterns are the result of the alleged AWP scheme, which renders his methodology unscientific and unreliable.

(102)   In Attachment F of his December 15, 2005 Declaration, Dr. Hartman presents pricing data for several NDCs of subject drugs showing AWP and his calculation of ASP. In his description of the pricing charts, Dr. Hartman asserts that the growing differences between AWP and ASP through time are the result of the alleged AWP scheme. For example in discussing Blenoxane, a chemotherapy drug sold by Bristol-Myers Squibb ("BMS"), Dr. Hartman states:

The data show that at the time of the first generic, the BMS spread for Blenoxane increased substantially. BMS maintained this spread by offering large discounts off of their WLP [wholesale list price, another name for WAC] prices hence increasing the spread available to physicians. Note that BMS increased its AWP at the time of the introduction of the first generic in

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[230] Berndt Report, p. 116.
[231] Hartman deposition, Volume IV, p. 938.
[232] Berndt Report, pp. 116–118.

1996. It maintained its AWP listing; however, it manipulated the spread by significantly increasing its discounts resulting in low ASPs.[233]

Based upon the differences between AWP and the ASP he calculates, Dr. Hartman asserts $1.9 million in damages for this NDC in his February 3, 2006 Addendum. However, Dr. Hartman fails to analyze, distinguish, or even acknowledge alternate explanations for the observed differences between AWP and ASP, including well-known legitimate price responses to competitive entry I discuss below. In fact, Dr. Hartman is not even aware of these legitimate explanations:

> Q. I'm asking whether you considered if there were [other possible alternate reasons why manufacturers would want there to be a spread between AWP and ASPs].
>
> A. I didn't—I didn't—I didn't—I didn't see any. I—I'd—the—in terms of—if you didn't have to compete on spread and in a spread that was not nontransparent, you're going to either uselessly raise your AWP—I mean if you don't have to compete on—if you don't have to use spread to compete, there's going to be no reason to raise your AWP. And so, I wouldn't see why anybody would just raise their AWP and perhaps invite scrutiny of—of the Justice Department. And I see no reason to lower what you're making per unit, the ASP, unless you were using it strategically. So, as a matter of economics, I don't see that there is any other reason. Doing either of those—of what you do to increase the spread would only get you in trouble, it seems to me.[234]

(103)   Notwithstanding Dr. Hartman's lack of familiarity, there are well-known and legitimate responses employed by manufacturers to compete with therapeutic and generic competition that are consistent with the observed patterns. For example:

- In his textbook *Healthcare Economics*, Feldstein states:

    ...when generic versions enter the market after the patent on a branded drug has expired, the branded drug loses market share to the generic drugs but the price of *the branded product actually increases*. The reason is that the price-sensitive customers switch to the generic drug, and those who do not switch

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[233]   Hartman Liability and Damages Declaration, Attachment F, p. 9.
[234]   Hartman deposition, Volume IV, pp. 1142–1143.

are not price-sensitive. Thus, the seller of the branded drug is able to raise its price.[235] [Emphasis in original.]

- In his textbook *Pharmaceutical Economics and Policy*, Schweitzer states:

  When generic products enter the marketplace, they typically appeal more to some buyers than to others. For example, HMOs and hospitals pharmacies are more likely to use generic products because they have the knowledge and expertise required to evaluate them, in contrast to individual physicians. One therefore expects that generic rivals will make greater sales inroads to some buyers than to others. That being so, producers of innovative products will respond to generic competition more strongly in some market segments than in others. By setting much lower prices where generic competition exists, and keeping prices at their original levels or even higher where generic competition is less important, the original sellers of many products have been able to maintain a large proportion of their original sales revenue even after patent expiration.[236]

Thus, the selective discounting that occurs as manufacturers face therapeutic and generic competition results in a legitimate increase in the differences between list prices (e.g., WAC) and ASP that is unrelated to the alleged AWP scheme. Therefore, since AWP is typically a formulaic markup above list price, manufacturers have a legitimate economic incentive to maintain and raise AWP, even as some providers receive substantial discounts.

(104)   These legitimate pricing incentives highlight the inappropriateness of Dr. Hartman's use of certain SSIDs that face no therapeutic competition to derive his yardsticks for drugs that face therapeutic and generic competition. In particular, Dr. Hartman asserts that the lack of therapeutic competition ensures that manufacturers would not have had the incentive to fraudulently manipulate the differences between AWP and ASP.[237] While this may be true, importantly however, the use of such SSIDs also ensures that Dr. Hartman's yardsticks do not

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[235] Feldstein, Paul J., *Health Care Economics, 6th Edition*, Thompson, Clifton Park, 2005, p. 310.
[236] Schweitzer, Stuart O., *Pharmaceutical Economics and Policy*, Oxford Press, New York, 1997, p. 105.
[237] Hartman Liability and Damages Declaration, p. 38.

reflect legitimate aspects of price competition when drugs do face therapeutic and generic competition. That is, while Dr. Hartman's yardsticks may be free from the effects of the alleged AWP scheme, they are also free from legitimate price effects that result from therapeutic and generic competition. Thus, Dr. Hartman's use of yardsticks based upon SSIDs facing no therapeutic competition to draw conclusions about drugs facing therapeutic and generic competition is inappropriate because it confounds the purported effects of the allege AWP scheme with legitimate competitive pricing factors.

(105)   My analysis of manufacturers' sales data confirms the existence of significant selective discounting consistent with the legitimate explanation for "spread" offered by economic theory.[238] Specifically, as shown in Table 9, for each of the 10 drugs I study, I find significant sales volume transacted at list price during the period in which Dr. Hartman purports to find liability and damages associated with the alleged AWP scheme.[239] Moreover, sales below list price can still be influenced by list price, which makes this measure a conservative illustration of the economic theory associated with selective discounting. Thus, on the basis of economic theory and empirical evidence, I conclude that Dr. Hartman's use of SSIDs that face no therapeutic competition as yardsticks for drugs facing therapeutic and generic competition confounds the purported effects from the alleged AWP scheme with well-known and legitimate competitive pricing factors and amounts to an assumption that the observed differences between AWP and ASP result from the alleged AWP scheme. Thus, I conclude that Dr. Hartman's yardstick methodology is unscientific and unreliable.

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[238]   In 1996, OIG also found that some providers paid as much as AWP for albuterol sulfate. See "Suppliers' Acquisition Costs for Albuterol Sulfate," Department of Health and Human Services Office of Inspector General, June 1996, p. 6.

[239]   See Appendix D for a discussion of the electronic data sources and procedures used in this analysis.

Table 9: Dollar sales and percent of total dollar sales transacted at list price

Manufacturer	Drug	Hartman liability	Sales at list price	Percent of revenue from sales at list price
AstraZeneca	Zoladex	1995–2002	$68,747,080	5%
Bristol-Myers Squibb	Blenoxane	1996–2002	$22,458,966	15%
	Cytoxan	1993–2002	$43,406,912	36%
	Etopophos	1996	$586,227	78%
	Paraplatin	1997–1999, 2001–2002	$189,630,112	28%
	Rubex	1994–2002	$1,686,788	33%
	Taxol	1998–1999, 2001–2002	$137,090,160	24%
	Vepesid	1993–2002	$48,640,136	20%
Johnson & Johnson	Procrit	1993, 1995–1999, 2002–2003	$595,264,768	15%
	Remicade	1998–2003	$3,046,344,192	95%
Schering-Plough	Intron	1991–1998, 2000–2004	$203,801,488	64%
	Proventil	1992–2004	$118,837,384	43%
	Temodar	2001–2004	$26,476,226	77%

Source: AstraZeneca, Bristol-Myers Squibb, Johnson & Johnson, and Schering-Plough Direct Sales and Chargeback tables; Medi-Span; Bristol-Myers Squibb and Johnson & Johnson wholesale list price files. Also see Hartman Liability and Damages Declaration, Appendix I.

(106)   Finally, I note that the observed patterns of AWP and ASP for many drugs are not consistent with a concerted effort to effectuate the AWP scheme plaintiffs allege. For example, I do not find a consistent pattern of "artificially inflated AWPs" among the 15 NDCs for the drug Procrit during the period 1991 to 2003, when Dr. Hartman purports to find liability and damages.[240] Specifically, in 1999, two Procrit NDCs had "spreads" slightly above 30 percent, while the other nine Procrit NDCs had "spreads" below 30 percent. Subsequently, in 2002, these two NDCs had "spreads" below 30 percent, while two other NDCs had "spreads" slightly above 30 percent. In fact, for every year in which Dr. Hartman finds liability for a Procrit NDC, he also finds that at least two thirds of all Procrit NDCs did not have "spreads" above 30 percent. These observations appear to reflect random fluctuations resulting from

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[240]   Hartman Liability and Damages Declaration, Attachment G.4.c.

variations in discounting and the mix of providers reflected in annual ASPs. Plaintiffs' experts have not offered any economic theory explaining how this pattern would be consistent with the manufacturer effectuating a concerted scheme.[241] To the contrary, Dr. Hartman acknowledges that this is not the type of pricing behavior his yardstick methodology is intended to implicate:

> ...we're talking about pricing strategies exploiting spreads. If I'm a manufacturer that has–you know, I'm flipping a coin and have one spread on one and a different spread on another, that's not a strategy and that's not the way these guys do their pricing and that's not what this model purports to get at.[242]

Moreover, I note that if Dr. Hartman's calculations of ASP were even slightly understated, he would likely not find liability for Procrit.

(107)   Similarly, I do not find a consistent pattern of "artificially inflated AWPs" for the single NDC of Remicade for which Dr. Hartman purports to find liability and damages from 1998 to 2003.[243] Specifically, according to Dr. Hartman's calculations, Remicade has "spreads" ranging from a low of 30.8 percent in 1998 to a high of 36.1 percent in 2001.[244] I note that Dr. Rosenthal characterizes the "spreads" for Remicade as follows:

> ...the spreads were maintained over the period by increases in the AWP for Remicade in step with increases in the ASP.[245]

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[241]   Similar patterns exist among Dr. Hartman's calculations for Intron A (Schering-Plough). Referring to these data, Dr. Rosenthal says: "The chart below shows the steady increase in both the AWP and the spread for one NDC of the Schering Plough drug, Intron A." See Rosenthal Liability Report, pp. 19–20. However, no such trend exists. In fact, Dr. Hartman's data shows that the difference between AWP and ASP for this NDC of Intron A actually falls from 1993 to 1996 (to 22 percent), and lies below the 30 percent threshold for seven years from 1994 to 2000. See Hartman Liability and Damages Declaration, Attachment G.5.c.

[242]   Hartman deposition, Volume IV, p. 1099.

[243]   Hartman Liability and Damages Declaration, Attachment G.4.c.

[244]   Hartman Liability and Damages Declaration, Attachment G.4.c.

[245]   Rosenthal Liability Declaration, p. 19.

Thus, Remicade also does not fit the pattern of a concerted scheme to lower provider acquisition costs and fraudulently inflate AWPs. Moreover, like Procrit, if Dr. Hartman's calculations of ASP were even slightly understated, he would likely not find liability or damages for Remicade.

V.2. Dr. Hartman's methodology is premised on a flawed assumption that TPPs expected AWP to be a signal for acquisition cost

(108)   Dr. Hartman's yardstick methodology is premised on an assumption that TPPs expected AWP to have a reasonably predictable relationship to acquisition costs. Dr. Hartman states:

> TPPs have looked for easily ascertainable rules of thumb or signals for expectations regarding reasonable claims for reimbursement of such physician administered drugs. Since Medicare has taken the lead with such reimbursement under Part B, it is not surprising that TPPs follow Medicare's lead. Reliance upon AWP has followed, as has the assumption that AWP provides a reasonable signal for ASP.[246]

(109)   As I demonstrate in Section IV.1, Dr. Hartman's assumption is incorrect. For example, many TPPs:

- Had information available to them, such as OIG reports, explicitly stating that AWP was not a reliable signal for acquisition costs.

- Purchased physician-administered drugs and therefore would have been aware of the widely varying differences between AWP and acquisition costs and would not have relied on AWP as a signal for acquisition costs.

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[246] Hartman Liability and Damages Declaration, p. 41. Similarly, Dr. Hartman states: "I find that TPPs must have and did look to signals for the costs of each of the factors (including the drugs administered) and services required during negotiations for contracts involving physician-administered drugs. ...If the signal is inflated for the actual costs of a given component (i.e., the AWP of the drug administered is inflated), commercial payors will be overcharged." See Hartman Liability and Damages Declaration, p. 24.

- Have explicitly stated they did not believe AWP bore a predictable relationship to acquisition costs.

Since Dr. Hartman's methodology requires that TPPs expected AWP to have a reasonably predictable relationship to acquisition costs, his methodology is therefore inapplicable to TPPs that did not have such expectations. In particular, Dr. Hartman's methodology assumes that payors would negotiate the same discounts from AWP in the but-for scenario. However, there is no reason to believe that payors who do not expect that AWP was a reliable signal for acquisition cost would negotiate as Dr. Hartman's methodology specifies. Therefore, Dr. Hartman's yardstick methodology is inappropriate.

V.3. Dr. Hartman's application of yardsticks is arbitrary and unreliable

(110)   In this section, I demonstrate the arbitrary and unreliable nature of Dr. Hartman's average expectation approach by applying his methodology using yardsticks that reflect the information available to payors during the class period. For example, I use the information from the 1992 and 1997 OIG reports, as well as information available to TPPs through their direct purchases of physician-administered drugs to construct alternative yardsticks. Doing so, I reduce the purported damages Dr. Hartman calculates by 40 to 99 percent for Classes 1 and 2 and by 27 to 99 percent for Class 3. I therefore conclude that Dr. Hartman's yardstick methodology is arbitrary, unreliable, and overstates the purported damages he calculates.

(111)   With respect to Medicare reimbursements under Classes 1 and 2, I begin by noting that in adopting a 30 percent yardstick for TPPs, Dr. Hartman acknowledges that payors expected AWP to exceed provider acquisition costs by as much as 30 percent. Nevertheless, he applies a zero percent yardstick for Medicare reimbursements. Yet, Medicare is the largest and one of the most sophisticated payors of all. In fact, several of the publicly available sources from which Dr. Hartman derives his yardsticks are based on research conducted by OIG on behalf of Medicare.[247] Therefore, it is more appropriate to assume that Medicare had, at a minimum,

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[247]   Hartman Liability and Damages Declaration, p. 16.

the same knowledge and expectations as the TPPs. In the first instance, therefore, I adjust Dr. Hartman's damage calculations to use the same 30 percent yardstick for Medicare reimbursements as he uses for TPPs. Based on this adjustment alone, I reduce the purported damages Dr. Hartman's calculates in his December 15, 2005 Declaration by $59 million or 40 percent.[248]

(112)   However, the previous adjustment fails to acknowledge that, based upon the 1992 and 1997 OIG reports, Medicare was aware of markups much higher than 30 percent. As I discussed in Section III.1, for example, the 1992 OIG report illustrates markups of as much as 488 percent. Therefore, I calculate the median reported markup over provider acquisition costs for all drugs in the 1992 and 1997 OIG reports. I also calculate the maximum reported markups.[249] Applying the greater of 30 percent and these yardsticks, I reduce the purported Class1 and Class 2 damages Dr. Hartman calculates in his December 15, 2005 Declaration by $69 million or 47 percent using the median and $146 million or 99 percent using the maximum. The effects from each adjustment are shown in Table 10.[250]

Table 10: Adjustments for purported damages to Classes 1 and 2

Expectation applied as yardstick	Dr. Hartman's purported damages	Adjusted damages	Reduction in damages	Percent reduction
30 percent yardstick	$147,140,932	$87,976,499	$59,164,433	40%
Greater of 30 percent and the median yardsticks from 1992 and 1997 OIG reports	$147,140,932	$77,708,237	$69,432,695	47%
Greater of 30 percent and the maximum yardsticks from 1992 and 1997 OIG reports	$147,140,932	$808,639	$146,332,293	99%

Source: Dr. Hartman's damage calculation materials in support of his December 15, 2005 Declaration; 1992 and 1997 OIG reports.

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[248]   The corresponding adjustment to Dr. Hartman's February 3 Addendum reduce the purported damages he calculates by 57 percent.

[249]   This approach is consistent with the approach Dr. Hartman employs with respect to single-source innovator drugs (i.e., applying the maximum of single-source drug "spreads" observed). See Hartman Liability and Damages Declaration, p. 40.

[250]   The corresponding adjustments to Dr. Hartman's February 3 Addendum reduces the purported damages he calculates by 62 percent for the median approach and 99 percent for the maximum approach.

(113)   Similar logic can be used to adjust Dr. Hartman's purported calculation of damages for Class
3. I first note that, as discussed in Section IV.1, TPPs gather knowledge about the differences
between AWP and provider acquisition costs from a variety of sources. Notably, all TPPs had
access to the publicly available OIG reports and many TPPs, including plaintiff BCBS-MA,
also purchase physician-administered drugs directly from manufacturers and wholesalers at
prices consistent with ASP. I make adjustments to Dr. Hartman's purported damage
calculations by employing alternative yardsticks based on the median and maximum markups
observed directly by TPPs through their drug purchases.[251] Doing so, I reduce Dr. Hartman's
damages by 27 percent and 69 percent respectively.[252] Separately, I apply the maximum OIG
yardsticks described above. Doing so, I reduce Dr. Hartman's damages by 99 percent. The
reduction in damages for each of these is shown in Table 11.[253]

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[251]   I begin by calculating the markup between each TPP's annual quantity weighted purchase price and Dr.
Hartman's AWP for every NDC and year where total annual sales are greater than $500. For NDCs and
years in which a TPP has no purchases, I repeat the last known markup, if available, on an NDC by NDC
basis. For each payor and year, I then calculate the median and maximum markup across NDCs. To
calculate each payor's annual median markup, I first calculate a median across NDCs for each drug and
then use these results to calculate a median across all drugs. If a given payor has no direct purchases in a
given year and all years prior, Dr. Hartman's 30 percent "but-for spread" is applied. Next, I apply each
TPP's median and maximum markups to a share of Class 3 units, based on shares of Massachusetts'
beneficiaries, and calculate purported damages. Finally, I sum damages across TPPs to arrive at Class 3
damages using each of the alternative yardsticks.

[252]   Because 30 percent of Massachusetts's beneficiaries are covered by payors not included in my analysis,
these approaches could yield no more than a 70 percent reduction in Dr. Hartman's damages. Damages
would be further reduced if any of the payors I do not include also expect the difference between AWP and
ASP to exceed Dr. Hartman's 30 percent yardstick.

[253]   The corresponding adjustments to Dr. Hartman's February 3 Addendum reduces the purported damages he
calculates by 27 percent for the median approach, 69 percent for the maximum approach, and 99 percent
for the OIG-report approach.

Table 11: Adjustments for purported damages for Class 3

Expectation applied as yardstick	Dr. Hartman's purported damages	Adjusted damages	Reduction in damages	Percent reduction
Median markup from TPP direct purchases	$24,984,948	$18,347,243	$6,637,705	27%
Maximum markup from TPP direct purchases	$24,984,948	$7,709,927	$17,275,021	69%
Greater of 30 percent and the maximum yardsticks from 1992 and 1997 OIG reports	$24,984,948	$165,300	$24,819,648	99%

Source: Dr. Hartman's damage calculation materials in support of his December 15, 2005 Declaration; 1992 and 1997 OIG reports.

(114)   Finally, I note that employing yardsticks that reflect information available to payors is only a start in addressing the unreliability of Dr. Hartman's methodology. Further adjustments are required to address the effects of payors' competitive leverage and their use of drug reimbursements to subsidize physician service fees as well as to address the legitimate economic pricing factors I discussed previously. In addition, as I discuss in the next section, additional adjustments are required to exclude transactions that were not based upon AWP.

V.4. Dr. Hartman erroneously applies overcharges to units not reimbursed based upon AWP

(115)   In certifying Class 3, Judge Saris has required applicable transactions to be reimbursed "under a contract that expressly uses AWP as a pricing standard."[254] In previous declarations, I concluded that identifying reimbursements based upon such contracts requires an individualized inquiry on a payor-by-payor, contract-by-contract and, in some instances, a transaction-by-transaction basis.[255] To investigate this question, however, Dr. Hartman analyzes reimbursement data for only a single payor and reviews a summary of contracts provided by plaintiffs' counsel. Dr. Hartman concludes:

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[254]   Consolidated Order, p. 5.

[255]   Gaier Declaration, Section IV.6 and Gaier Sur-Reply Declaration, Section VII.

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Based upon these data, I find no evidence to defeat the conclusion that substantially all claims for which allowed amounts are reimbursed will be included in my aggregate damage calculation.[256]

However, a more thorough review of the available evidence demonstrates that a significant portion of reimbursements would not have been based upon AWP as a pricing standard. Dr. Hartman's failure to identify and exclude such reimbursements renders his methodology unreliable and causes him to overstate the purported damages he calculates by an amount unknowable without substantial individualized inquiry.

(116)   Dr. Hartman's damage calculations are based upon the manufacturers' sales data. However, manufacturers' sales data cannot identify which sales were reimbursed based upon AWP and which were not. Dr. Hartman purports to address this issue by analyzing reimbursement data for five drugs (Zoladex, Taxol, Zofran, Remicade, Intron A), for a single year (1998), from a single payor (Blue Cross Blue Shield of Kansas City ("BCBS-KC")). On the basis of this analysis, Dr. Hartman concludes that the percentage of reimbursements potentially not based upon AWP—which he terms "unclear"—ranges from four to 11 percent. Dr Hartman conjectures that unclear reimbursements result from claims that "reflect coinsurance amounts on hospital out-patient administration for the most part," which he purports to exclude from his damage calculations by excluding manufacturers' sales to hospitals.[257] The result is that Dr. Hartman's damage calculations include all manufacturers' sales to "physicians, physician groups, oncology groups, clinics, long-term care facilities, nursing homes, and certain others."[258]

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[256] Hartman Liability and Damages Declaration, p. 31.

[257] Hartman Liability and Damages Declaration, p. 30.

[258] Hartman Liability and Damages Declaration, p. 43. Dr. Hartman states that after units sold to hospitals are removed, "The majority of the remaining claims are determined by the AWP of the NDC administered or the AWP of the multiples of the fundamental unit administered." Hartman Liability and Damages Declaration, p. 29.

(117)   As I discussed in my previous declarations, however, there are a variety of reasons to expect that a significant portion of manufacturers' sales to non-hospital providers would not be reimbursed based upon AWP as a pricing standard.[259] For example:

- Reimbursements may be based upon provider's billed charges, especially for indemnity plans and out-of-network reimbursements under managed-care plans.

- Providers administer drugs to uninsured patients for which payment is typically based upon billed charges or in some instances not made at all.

- Reimbursements may be made pursuant to capitated contracts that pay providers a fixed amount per member per month, regardless of utilization.

- Reimbursements may be subject to withhold or risk-sharing agreements in which over-target reimbursements are adjusted at year end.

Accordingly, a more thorough review of the available evidence is required to identify transactions that were reimbursed "under a contract that expressly uses AWP as a pricing standard."[260]

(118)   I begin by testing Dr. Hartman's conjecture that the "unclear" transactions in the BCBS-KC claims data are associated with hospital reimbursements.[261] Specifically, for the transactions Dr. Hartman classifies as unclear, I match the indicated tax identification number to provider names using publicly available information.[262] Contrary to Dr. Hartman's conjecture, I find that many of the indicated providers are not hospitals (see Table 12 for a partial list). Indeed, many of these providers appear in the manufacturers' sales data under non-hospital customer categories.[263]

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[259] Gaier Declaration, Section IV.6 and Gaier Sur-Reply Declaration, Section VII.

[260] Consolidated Order, p. 5.

[261] See Appendix D for a discussion of the electronic data sources and procedures used to conduct the analyses presented in this section.

[262] See, for example, the tax identification number database at www.knowx.com.

[263] For example, customer codes listed in the GlaxoSmithKline sales data (i.e., the "TC" field) for the following providers are not excluded by Dr. Hartman, despite their association with "unclear" reimbursements: Apria Healthcare (30-home health), Coram Alternative Site Services (30-home health), Heartland Hematology-Oncology Associates (45-oncology clinic), Hope Cancer Institute (45-oncology clinic), Kansas City Internal Medicine (45-oncology clinic), St. Joseph Oncology (45-oncology clinic). See

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Table 12: Non-hospital providers reimbursed at "unclear" amounts

Provider name	
Apria Healthcare	Morris F. Wise, MD
Cardiology Services	Myers & Abercrombie, MDs
Coram Alternative Site Services	Oncology & Hematology Associates of Kansas City
Heartland Hematology-Oncology Associates	Russell E. Tackett, MD
Hope Cancer Institute	St. Joseph Oncology
Kansas City Internal Medicine	Therapeutic Radiologists
Lentz, Biber, & Wilson, MDs	Urology Chartered
Mark J. Brodkey, MD	

(119)   To test Dr. Hartman's conjecture further, I apply his methodology to more comprehensive reimbursement data from Oxford Health, in which hospital outpatient reimbursements, reimbursements to PBMs, and reimbursements under the Medicare context are explicitly identified and can be appropriately excluded.[264] Having excluded these claims, and restricting my attention to the drugs and years analyzed by Dr. Hartman for the BCBS-KC data, I conclude that the percentage of non-hospital reimbursements that Dr. Hartman's methodology would characterize as "unclear" ranges from seven to 16 percent (see Table 13).[265] Therefore, on the basis of my analysis of the BCBS-KC and Oxford claim data, I conclude that Dr. Hartman's conjecture that unclear transactions result from reimbursements for hospital outpatient administration is incorrect. It therefore follows that, despite excluding hospital transactions from the manufacturers' sales data, Dr. Hartman still calculates damages for numerous transactions that were not based upon AWP as a pricing standard.

Hartman Liability and Damages Declaration, Attachment G.3.D, pp. 2–3.

[264]   In my analysis of Oxford data, I include the following provider types: Office, Home, Custodial Care Facility, End Stage Renal Disease, Homeless Shelter, Independent Lab, Nursing Facility, Skilled Nursing Facility. I exclude reimbursements to the following PBMs that I identified in Oxford Health data: Caremark and Direct Script (Oxford Health's wholly owned mail-order pharmacy subsidiary during 1998). I also exclude claims reimbursed in the Medicare context, identified by adjustment code A27, "Requested Amount if Medicare Approved."

[265]   These results do not vary significantly when including reimbursements to PBMs and claims potentially reimbursed in the Medicare context. The percentage of the non-hospital reimbursements that Dr. Hartman's methodology would characterize as "unclear" would range from five to 14 percent.

Table 13: "Unclear" reimbursements to non-hospital providers according to Dr. Hartman's methodology applied to Oxford Health data

Drug	HCPCS code	"Unclear" reimbursements
Intron	J9214	16%
Remicade	J1745	7%
Taxol	J9265	11%
Zofran	J2405	11%
Zoladex	J9202	11%

Source: Oxford Health Plan claims data. Analysis is restricted to years and drugs in Dr. Hartman's Table 4. Includes providers described as Office, Home, Custodial Care Facility, End Stage Renal Disease, Homeless Shelter, Independent Lab, Nursing Facility, and Skilled Nursing Facility. Excludes claims from Direct Script and Caremark (PBMs), and claims in Medicare context. The "identifiable percentages of AWP" used in this analysis were the most frequently occurring percentages falling within 90–105 percent of any AWP.

(120)   Setting aside the "unclear" reimbursements in Dr. Hartman's analysis of BCBS-KC data, the remaining reimbursements constitute those that Dr. Hartman concludes were based upon AWP. However, in analyzing the remaining claims, I find that in as much as 50 percent of the total units reimbursed for the drugs Dr. Hartman analyzes, the allowed amount equals the billed charge. It is therefore reasonable to conclude these reimbursements are based upon the providers' billed charges. In Table 14, I show the percentage of units in which the allowed amount equals the billed charge for BCBS-KC and three other payors, including plaintiff BCBS-MA.

Table 14: Units from claims with an allowed amount equal to billed charge

Drug	HCPCS code	BCBS-KC	BCBS-MA	Cigna	Oxford
Intron	J9214	48%	9%	21%	7%
Remicade	J1745	3%	4%	10%	15%
Taxol	J9265	13%	2%	10%	17%
Zofran	J2405	14%	5%	21%	10%
Zoladex	J9202	39%	3%	20%	50%

Source: Analysis is restricted to years and drugs in Dr. Hartman's Table 4. Due to data constraints, Cigna Medical results are based on 2002 data. Medicare-related claims excluded for BCBS-KC, Cigna Medical, and Oxford Health (no data available for BCBS-MA). Oxford Health data excludes hospital and PBM reimbursements (see Table 13).

(121)   As shown in Table 14, a significant portion of reimbursements is apparently based upon billed charges. Such observations raise the question of whether the providers' billed charges are based upon AWP. The answer to this question requires an individualized inquiry. However, the prevalence of indemnity plans and out-of-network transactions under managed care during the class period raises significant concerns that numerous transactions would not have been based upon AWP as a pricing standard. In particular, under indemnity plans and for out-of network reimbursements under managed care, reimbursements are typically set by providers according to usual and customary fees. For example, a *New England Journal of Medicine* article states:

> With indemnity insurance, the patient chose a physician from among all those in the community, received care and a bill, and then submitted the bill to the insurer. Insurers had to pay fees that were 'usual and customary' in each community, which meant that the local physicians set the fees.[266]

(122)   I note that indemnity insurance constituted nearly 50 percent of all health plan enrollment for insured individuals during the earlier portion of the class period.[267] I also note that until 1995, for example, plaintiff BCBS-MA reimbursed providers at billed charges, which were capped based upon "usual and customary" amounts set by providers.[268] With respect to out-of network reimbursements, I note that between three and 10 percent of the BCBS-KC units Dr. Hartman analyzes were administered by out-of-network providers. For Cigna, between 10 and 18 percent of these drugs are administered by out-of-network providers (see Table 15).

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[266]   R. Adams Dudley and Harold S. Luft, "Managed Care in Transition," *Health Policy 2001—The New England Journal of Medicine*, April 5, 2001, Volume 344, Number 14, p. 1087, available online at http://ptmanager.com/nejm%20managed%20care%20in%20transition%2004%202001.pdf.

[267]   Kaiser Family Foundation and Health Research and Educational Trust, "Kaiser Family Foundation and Health Research and Educational Trust, Employer Health Benefits: 2002 Annual Survey," p. 69.

[268]   Mulrey deposition, p. 58.

Table 15: Units administered by out-of-network providers

Drug	BCBS-KC	Cigna
Intron	10%	12%
Remicade	3%	10%
Taxol	4%	14%
Zofran	6%	17%
Zoladex	4%	18%

Source: Analysis is restricted to years and drugs in Dr. Hartman's Table 4. Due to data constraints, Cigna Medical results are based on 2002 data. Excludes Medicare-related claims.

(123)   Furthermore, by relying on manufacturers' sales data, Dr. Hartman fails to exclude units administered to uninsured individuals. Dr. Hartman has previously conceded that such transactions are "certainly not subject to any contract referencing AWP" and "their payments are not to be included in any measure of damages."[269] Uninsured individuals have constituted approximately 15 percent of the U.S. population throughout the class period.[270] In Massachusetts, uninsured individuals accounted for between eight and 13 percent of the population during the class period.[271] Despite Dr. Hartman's concession that transactions for uninsured patients should be excluded from his damage calculations, Dr. Hartman makes no adjustment to the manufacturers' sales data.

(124)   The evidence also demonstrates that many payors reimburse providers for drugs under capitated contracts, which would not have been based upon AWP. TPPs in Massachusetts and elsewhere utilized capitation arrangements for reimbursements of physician-administered drugs during the class period.[272] For example, plaintiff BCBS-MA maintains a capitated contract that includes physician-administered drugs with Riverbend, a physician group.[273] In

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[269] Hartman Rebuttal Declaration, p. 8 and footnote 2.

[270] "U.S. Census Bureau: Historical Health Insurance Tables," available online at http://www.census.gov/hhes/www/hlthins/historic/hihistt1.html.

[271] "U.S. Census Bureau: Historical Health Insurance Tables," available online at http://www.census.gov/hhes/www/hlthins/historic/hihistt4.html.

[272] Approximately 25 to 50 percent of capitation arrangements in the mid to late 1990s included drug reimbursement as part of the capitated fee. See Kongstvedt, Peter R., *The Managed Health Care Handbook, Fourth Edition*, Aspen Publishers, Inc., 2001, p. 120.

[273] Mulrey deposition, p. 39.

addition, based on surveys conducted in the mid 1990s through early 2000s, 10 to 14 percent of physicians indicated that more than half of their patient-care revenue was derived from capitated or similar prepaid arrangements.[274]

(125)   As explained above, payors may also introduce contractual withholds in order to align incentives with providers. These contracts, even if referencing AWP, are intended to keep total reimbursements close to specified targets. Since over-target reimbursement totals are adjusted at year-end, withholds may effectively act as capitation or fixed fee contracts, breaking the link between reimbursements and AWP. A survey among managers of HMOs states that two thirds of HMOs use withholds, which are mostly between 11 to 20 percent of total income.[275]

(126)   On the basis of a more thorough review of the available evidence, I conclude that a significant portion of reimbursements would not have been based upon AWP as a pricing standard. I conclude that Dr. Hartman's failure to identify and exclude such reimbursements renders his methodology unreliable and causes him to overstate the purported damages he calculates by an amount unknowable without substantial individualized inquiry.
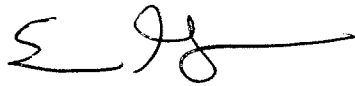
V.5. Conclusion

(127)   On the basis of his failure to account for well-known and legitimate features of price competition in many markets including pharmaceutical markets, his assumption that TPPs believed that AWP was a reliable predictor of acquisition costs, the arbitrary and unreliable nature of his yardsticks, and his failure to exclude transactions not based upon AWP as a

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[274]   Community Tracking Study Physician Survey, 1996–1997, ICPSR 2597; Community Tracking Study Physician Survey, 1998–1999, ICPSR 3267; Community Tracking Study Physician Survey, 2000–2001, ICPSR 3820. In all years surveyed, over 50 percent of providers had some patient care revenue that was paid on a capitated or prepaid basis. See http://search.icpsr.umich.edu/HMCA/query.html?col=abstract&op0=%2B&tx0=community+tracking+stud y+series&ty0=p&fl0=series%3A&op1=&tx1=restricted&ty1=w&fl1=availability%3A&op2=+&tx2=HMC A&ty2=w&fl2=archive%3A&nh=50&rf=3.

[275]   Hillman, Pauly, Kerman, and Martinek, "HMO Managers' views on financial incentives and quality," *Health Affairs*, Winter 1991, p. 210.

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pricing standard, I conclude that Dr. Hartman's yardstick methodology is unscientific, unreliable, and overstates the purported damages he calculates.

I declare under penalty of perjury that this declaration is true and correct.

Eric M. Gaier, Ph.D.

March 21, 2006

Date

Appendix A: Materials considered

Court Orders

- *Consolidated Order Re: Motion for Class Certification*, U. S. District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257-PBS, January 30, 2006

- *Memorandum and Order Re: Motion for Class Certification*, U. S. District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257, August 16, 2005

Declarations and Reports

- *Declaration of Eric M. Gaier, Ph.D. in Support of Defendants' Opposition to Class Certification*, U. S. District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257-PBS, October 25, 2004

- *Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calculation of Damages*, U. S. District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257-PBS, December 15, 2005

- *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, U. S. District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257-PBS, September 3, 2004

- *Liability Report of Dr. Meredith Rosenthal*, December 15, 2005

- *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, U. S. District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257, December 16, 2004

- *Report of Independent Expert Professor Ernst R. Berndt to Judge Patti B. Saris*, U. S. District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257-PBS, February 9, 2005

- *Supplemental Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calculation of Damages: Addendum*, U. S. District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257-PBS, February 3, 2005

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Appendices

- *Sur-Reply Declaration of Eric M. Gaier, Ph.D. in Support of Defendants' Opposition to Class Certification,* U. S. District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257-PBS, January 21, 2005

Depositions

- Austen, Karla: Health Net

- Beaderstadt, Mike: John Deere Health

- Brown, Mickey: BCBS-Mississippi

- Cizauskas, Sheila: BCBS-Massachusetts

- Demaina, Denise: BCBS-Massachusetts

- Devaux, Deborah: BCBS-Massachusetts

- Fox, Steven: BCBS-Massachusetts

- Goldman, Hal: Vista Healthplan

- Gorman, Lisa: BCBS-Massachusetts

- Hartman, Raymond, Volume I: Plaintiff Expert

- Hartman, Raymond, Volume II: Plaintiff Expert

- Hartman, Raymond, Volume III: Plaintiff Expert

- Hartman, Raymond, Volume IV: Plaintiff Expert

- Hartman, Raymond, Volume V: Plaintiff Expert

- Herbold, Jill: CIGNA

- Killion, John: BCBS-Massachusetts

- Lemke, Edward: Humana

- Mulrey, Michael: BCBS-Massachusetts

- Rosenthal, Meredith, Volume I: Plaintiff Expert

- Rosenthal, Meredith, Volume II: Plaintiff Expert

- Spahn, Joseph: Anthem Midwest

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- Thomas, David: Three Rivers Health Plans

Documents obtained through discovery

- A-VA 03010065–A-VA 03010068

- AET 004431–AET 004461

- AWP041-0943–AWP041-0946

- BCBS-MA-AWP-11599–BCBS-MA-AWP-11609

- BCBS-MA-AWP-12677–BCBS-MA-AWP-12678

- BCBS-MA-AWP-11976–BCBS-MA-AWP-12001

- HHC001-363

- HHC908-1217–HHC908-1218

- HUM 2258–HUM 2280

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Government documents

- Center for Medicare and Medicaid Studies, "Medicare Beneficiaries Enrolled by Census Region, Division and State 1985–1995"

- Center for Medicare and Medicaid Studies, "Medicare Beneficiaries Enrolled by Census Region, Division and State 1996–1999"

- Center for Medicare and Medicaid Studies, "Medicare Beneficiaries Enrolled by State as of July 1, 1999–2003"

- Center for Medicare and Medicaid Studies, "Medicare Enrollment—All Beneficiaries as of July 2001"

- Center for Medicare and Medicaid Studies, "Medicare Enrollment—All Beneficiaries as of July 2002"

- Center for Medicare and Medicaid Studies, "Medicare Enrollment—All Beneficiaries as of July 2003"

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- Center for Medicare and Medicaid Studies, "Medicare Enrollment: National Trends 1966–2003, Hospital and/or Supplementary Medical Insurance"

- Center for Medicare and Medicaid Studies, "Medicare Enrollment: National Trends 1966–2003, Supplementary Medical Insurance"

- Center for Medicare and Medicaid Studies, "National Health Expenditures by Types of Service and Source of Funds: Calendar Years 2004–1960"

- Center for Medicare and Medicaid Studies, "Medicare Part B Physician/Supplier National Data - Calendar Year 2003: Expenditures and Services by Specialty"

- Centers for Medicare and Medicaid Services, "Medicare Participating Supplier or Physician Agreement, CMS-460," October 2005

- Community Cancer Preservation Act of 2005, House of Representatives

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- Department of Health and Human Services, Office of Inspector General, "Excessive Medicare Payments for Prescription Drugs," December 1997

- Department of Health and Human Services, Office of Inspector General, "Adequacy of Medicare Part B Drug Reimbursement to Physician Practices for the Treatment of Cancer Patients," September 2005

- Department of Health and Human Services, Office of Inspector General, "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs," November 1998

- Department of Health and Human Services, Office of Inspector General, "Medicare Reimbursement of Prescription Drugs," January 2001

- Department of Health and Human Services, Office of Inspector General, "Physicians' Costs for Chemotherapy Drugs," November 1992

- Department of Health and Human Services, Office of Inspector General, "Suppliers' Acquisition Costs for Albuterol Sulfate," June 1996

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- Department of Health and Human Services, Office of Inspector General, "Use of Average Wholesale Prices in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program," October 1989

- Department of Health and Human Services, Treasury Department, "Health and Human Services Department, Centers for Medicare & Medicaid Services, Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B," March 4, 2005

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- Federal Register 39(230), November 27, 1974

- Federal Register 40(159), August 15, 1975

- Federal Register 56(227), November 25, 1991

- Federal Register 69(219), November 15, 2004

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Electronic data

AstraZeneca

- Direct sales data

    - cnt_mgt_zoladex_direct_sales

        - AZ0682114

- Chargeback data

    - cntmgt_pulmicortresp_indirect_sales

        - AZ0466414

    - cntmgt_zoladex_indirect_sales

        - AZ0682114

- Customer information

    - AZ_Sales_Based_Customers.csv

        - Produced by Dr. Hartman on February 3, 2006

Bristol-Myers Squibb

- Direct sales data

    - Direct.txt

        - BMS/AWP/001483004-14

- Chargeback sales data

    - Indirect.txt

        - BMS/AWP/001483004-14

    - OTN.txt

        - BMS/AWP/001483004-14

- Wholesale list price ("WLP") information

    - PricingRevised.xls

        - No Bates number given

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GlaxoSmithKline

- Chargeback sales data
  - ORS: cn_sales_v
    - GSK-MDL-STD00-0000001-06
    - GSK-MDL-SD01-0000001-172
  - IMHC: tcbline
    - GSK-MDL-STD00-0000001-06
    - GSK-MDL-SD01-0000001-172
- Customer information
  - ORS: cn_bu_v1
    - GSK-MDL-STD00-0000001-06
    - GSK-MDL-SD01-0000001-172
  - IMHC: trpcustmst
    - GSK-MDL-STD00-0000001-06
    - GSK-MDL-SD01-0000001-172

Johnson & Johnson

- Direct sales data
  - daf1994_p
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  - daf1995_p
    - MDL-HCS00013635
  - daf1996_p
    - MDL-HCS00013635
  - daf1997_p
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- daf1998_p
  - MDL-HCS00013635
- daf1999_p
  - MDL-HCS00013635
- daf2000_p
  - MDL-HCS00013635
- daf2001_p
  - MDL-HCS00013635
- daf2002_p
  - MDL-HCS00013635
- daf_data_2003
  - MDL–HCS00275971
- Chargeback sales data
  - imhc_jan_obi_p
    - MDL-HCS 00013630-13631
  - imhc_missing_2_days_send_11112004
    - MDL-HCS00282702
  - obi_1999_p
    - MDL-HCS00013632
  - obi_2000_p
    - MDL-HCS00013632
  - obi_2001_p
    - MDL-HCS00013632
  - obi_2002_p
    - MDL-HCS00013633

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- obi_2003
  - MDL-HCS00275988
- supplemental_cbks_procdt2004_to_20050511_2003before_invoice
  - MDL-HCS00282702
- dmcr_chargeback_p
  - MDL-HCS00013634
- chargebacks 2003 for awp
  - MDL-CEN00108048
- Whole list price information
  - 2005_11.30_Procrit-Remicade_FDB.Pricing.xls
    - No Bates number given

Schering-Plough

- Direct sales data
  - schering_direct_sales
    - SPW 0032447
- Chargeback sales data
  - schering_chargeback_1991_1994
    - SPW 0032448
  - schering_chargeback_1995_1998
    - SPW 0032448
  - schering_chargeback_1999_2001
    - SPW 0032448
  - schering_chargeback_2002_2004
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- http://www.uspharmacist.com/index.asp?show=article&page=8_1148.htm

Appendix B: Additional examples of drugs purchased by Massachusetts TPPs[276]
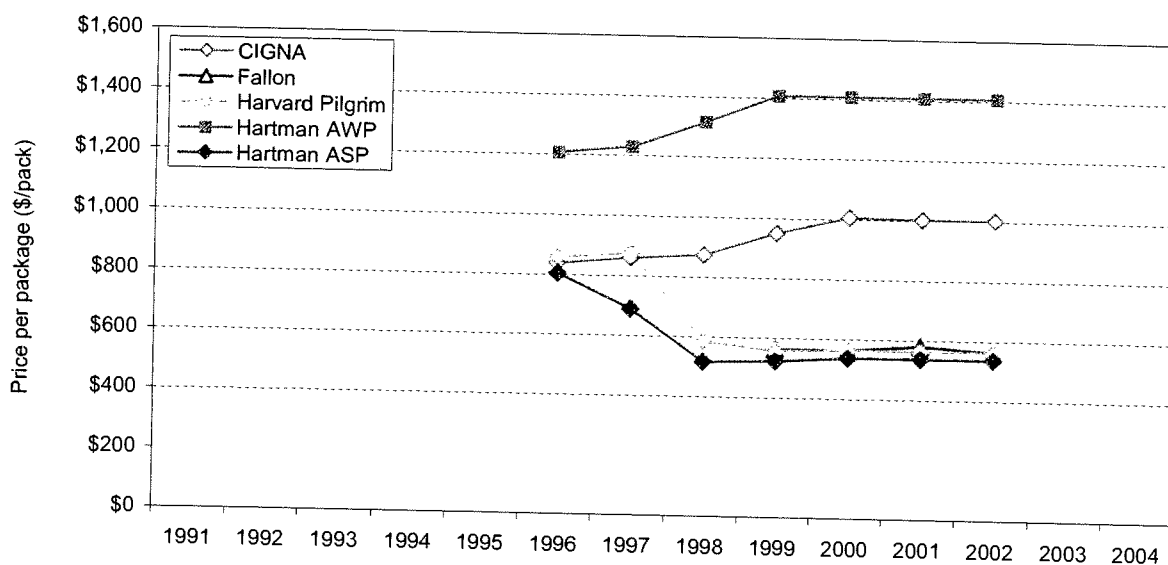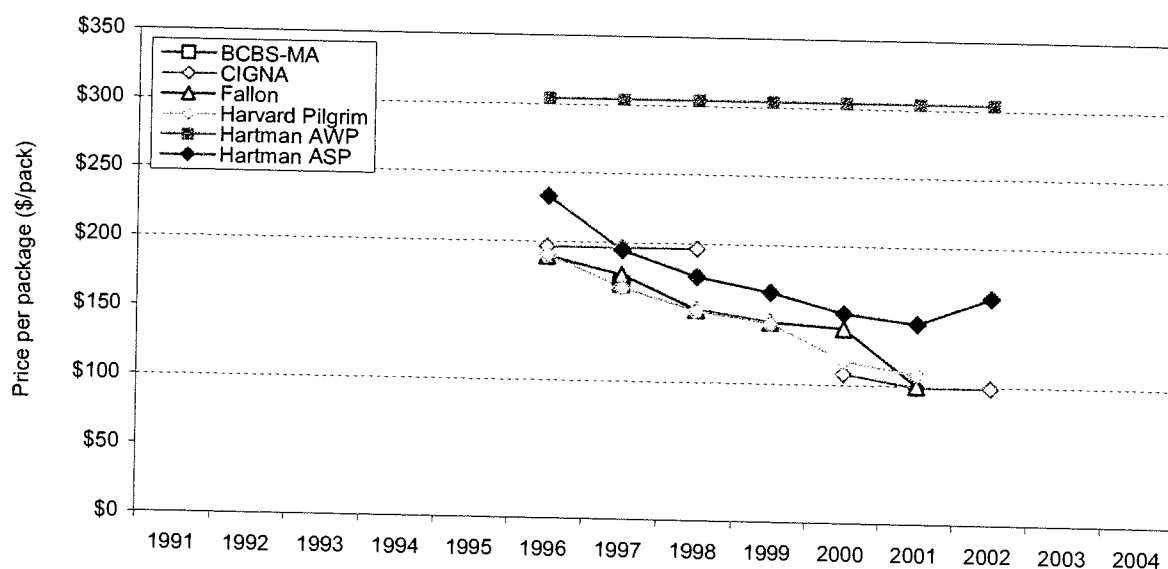
AstraZeneca[277]

Figure 8: Pulmicort (NDC 00186198804)

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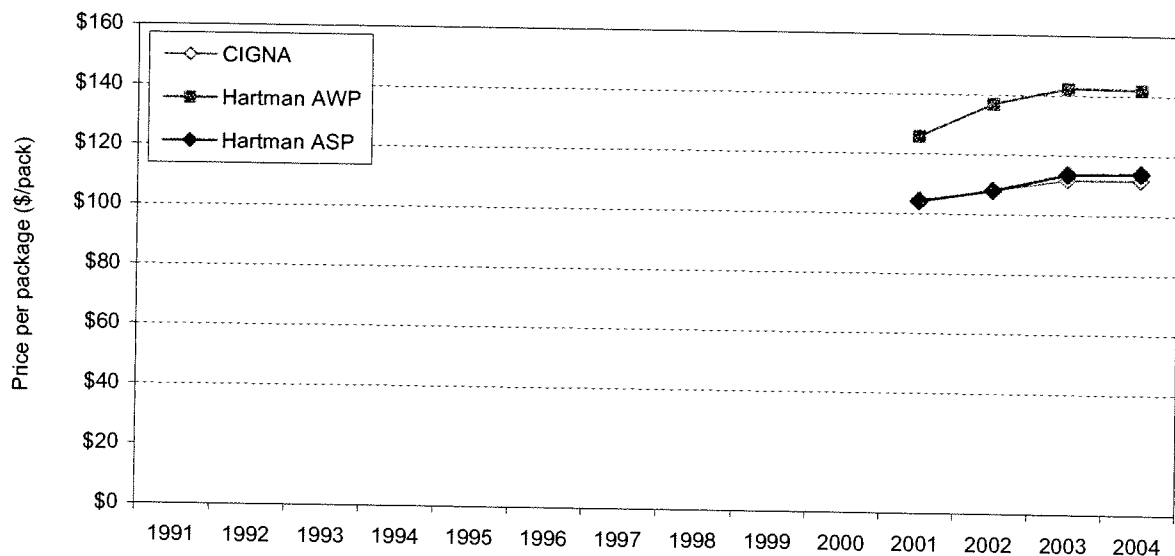
[276]   See Appendix D for explanation of the calculation of dollars and prices to Massachusetts TPPs.
[277]   Source: AstraZeneca indirect sales table.

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Figure 9: Zoladex (NDC 00310096130)

Bristol-Myers Squibb[278]

Figure 10: Blenoxane (NDC 00015301020)

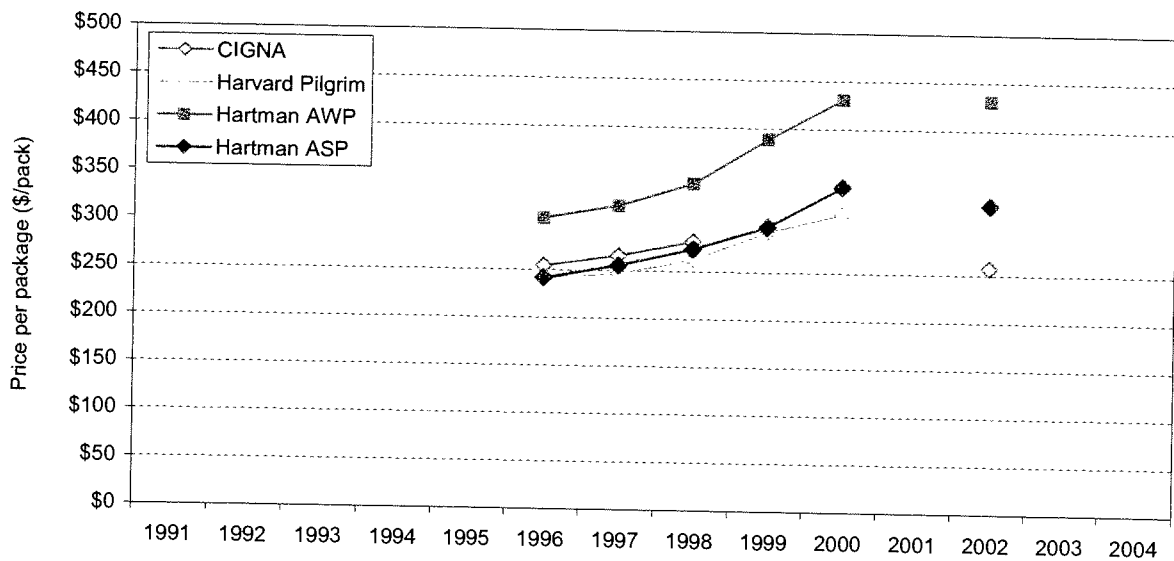

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[278]   Source: Bristol-Myers Squibb indirect sales data.

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Figure 11: Cytoxan (NDC 00015050301)

Figure 12: Cytoxan (NDC 00015054841)

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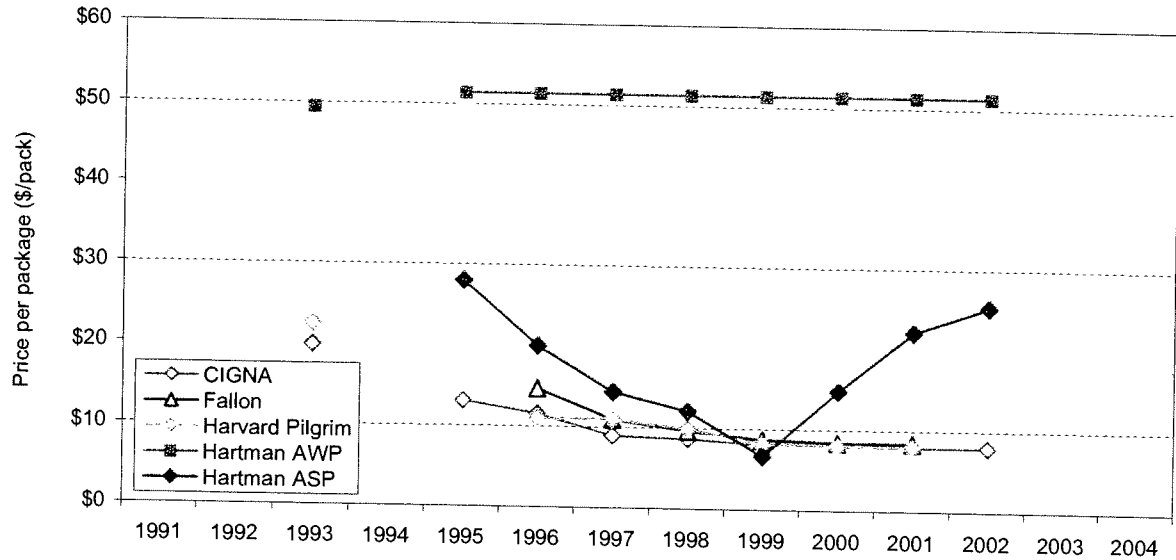
Figure 13: Paraplatin (NDC 00015321530)
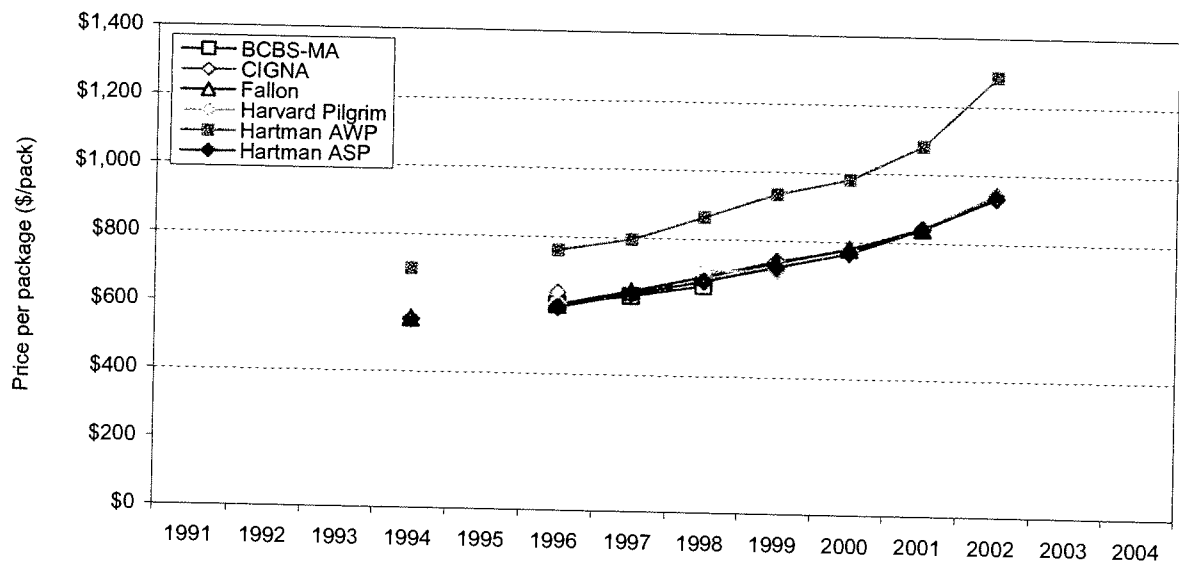
Figure 14: Vepesid (NDC 00015309145)

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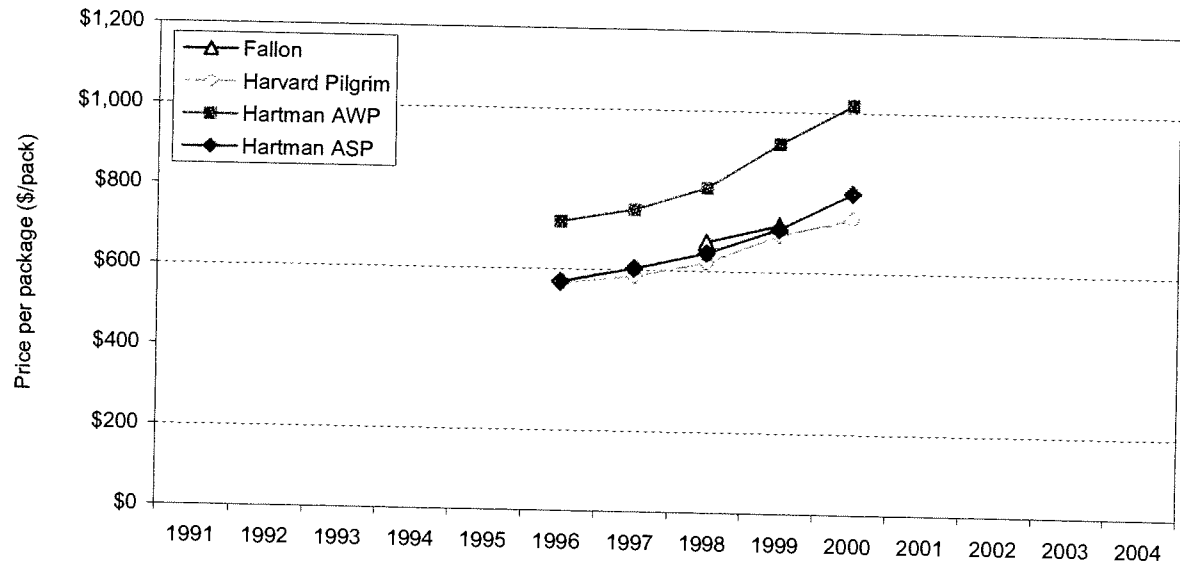
GlaxoSmithKline[279]

Figure 15: Kytril (NDC 00029414901)
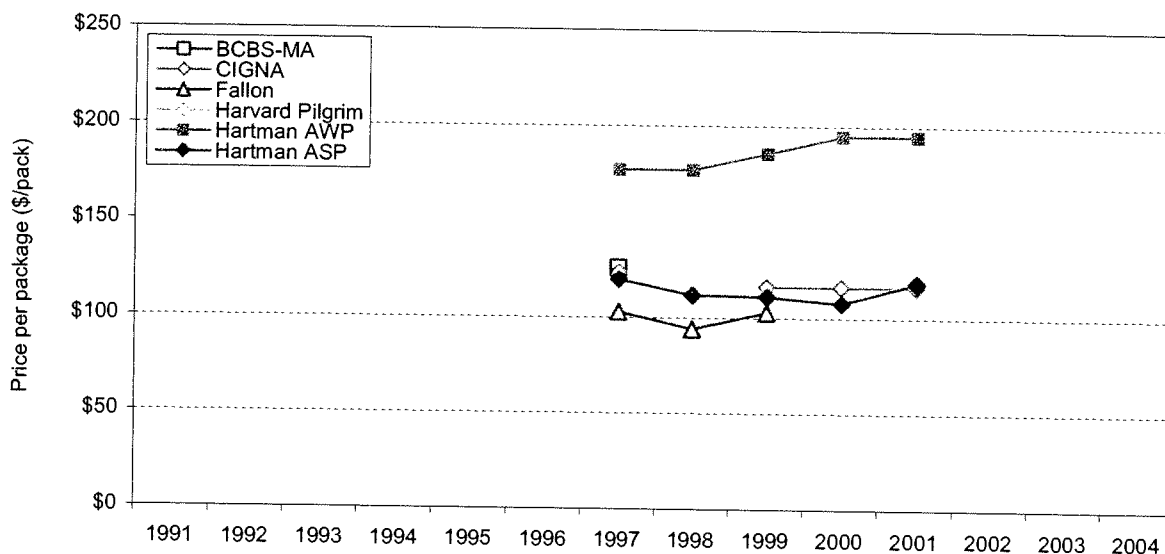
Figure 16: Kytril (NDC 00029415105)

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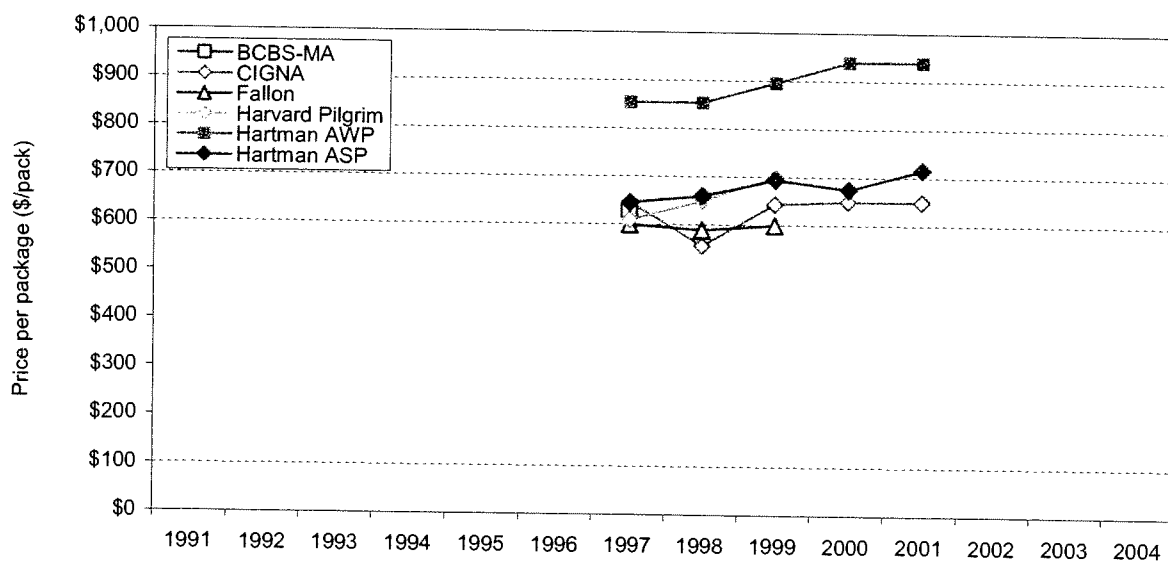
[279]   Source: GlaxoSmithKline indirect sales tables.

Figure 17: Zofran (NDC 00173044202)
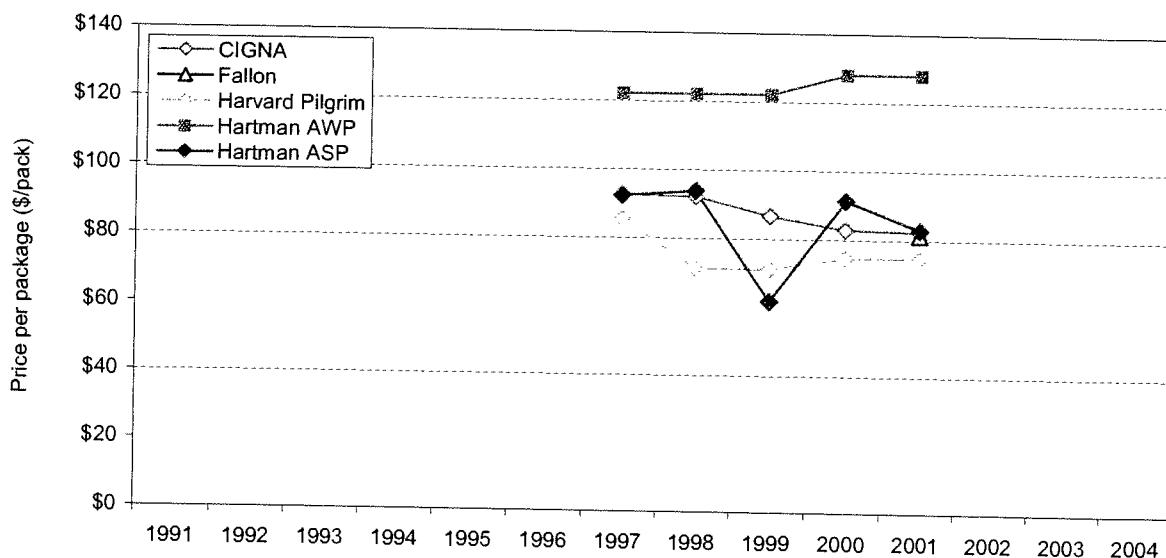
Johnson & Johnson[280]

Figure 18: Procrit (NDC 59676030401)

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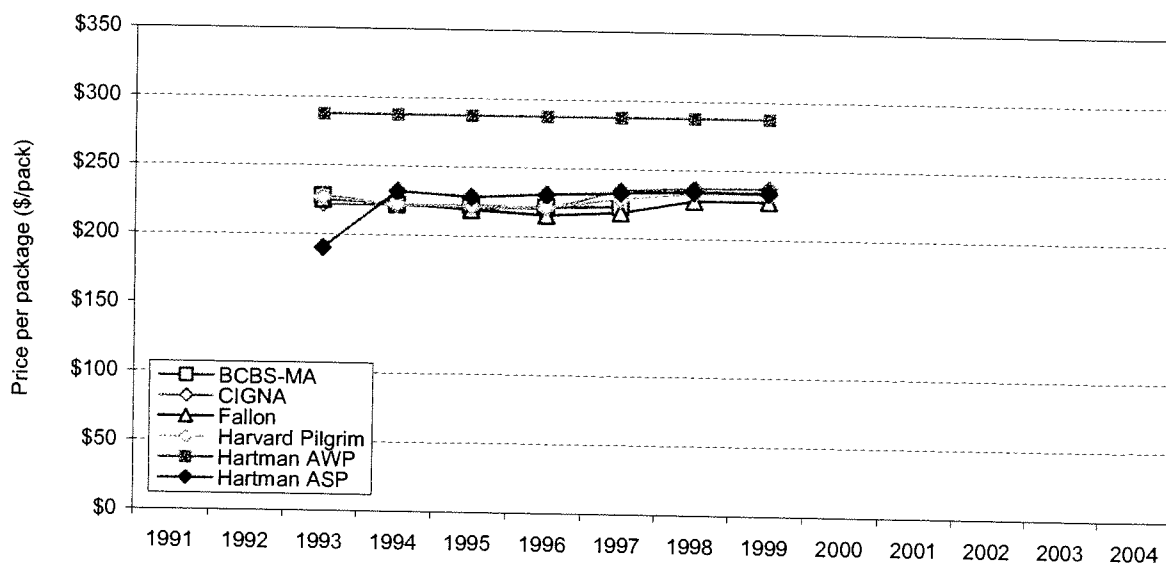
[280]   Source: Johnson & Johnson indirect sales table.

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Figure 19: Procrit (NDC 59676031001)
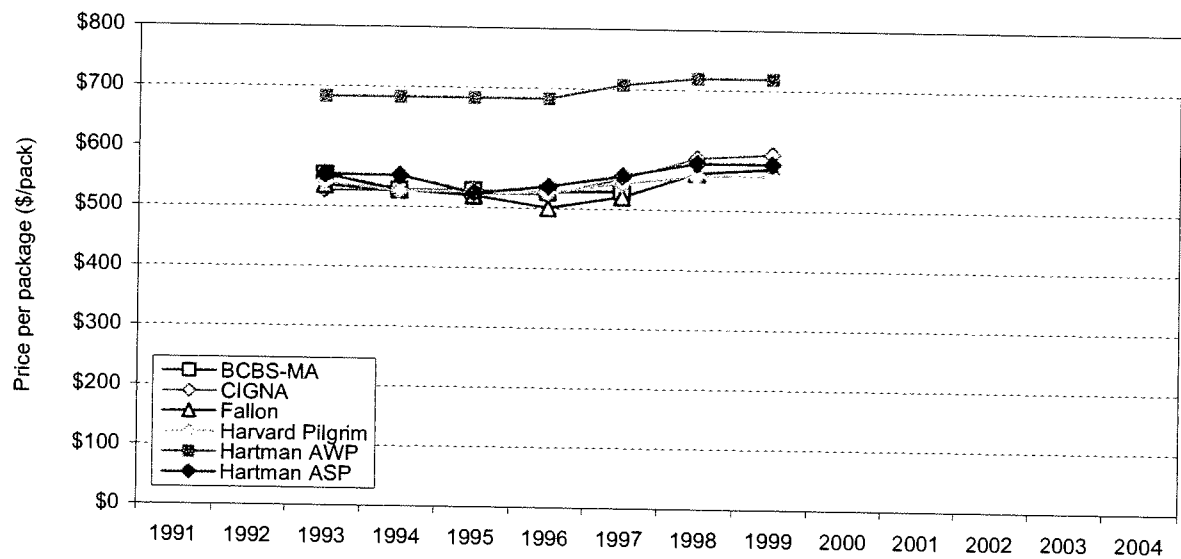
Figure 20: Procrit (NDC 59676032001)
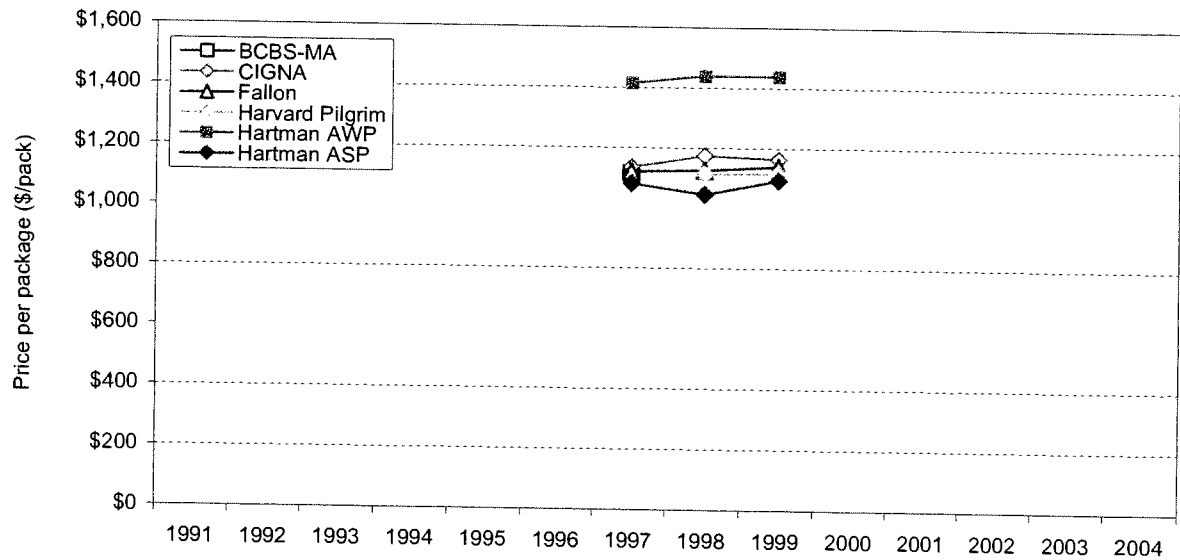
Schering-Plough[281]

Figure 21: Albuterol (NDC 5993015008)

Figure 22: Intron (NDC 00085076901)[282]

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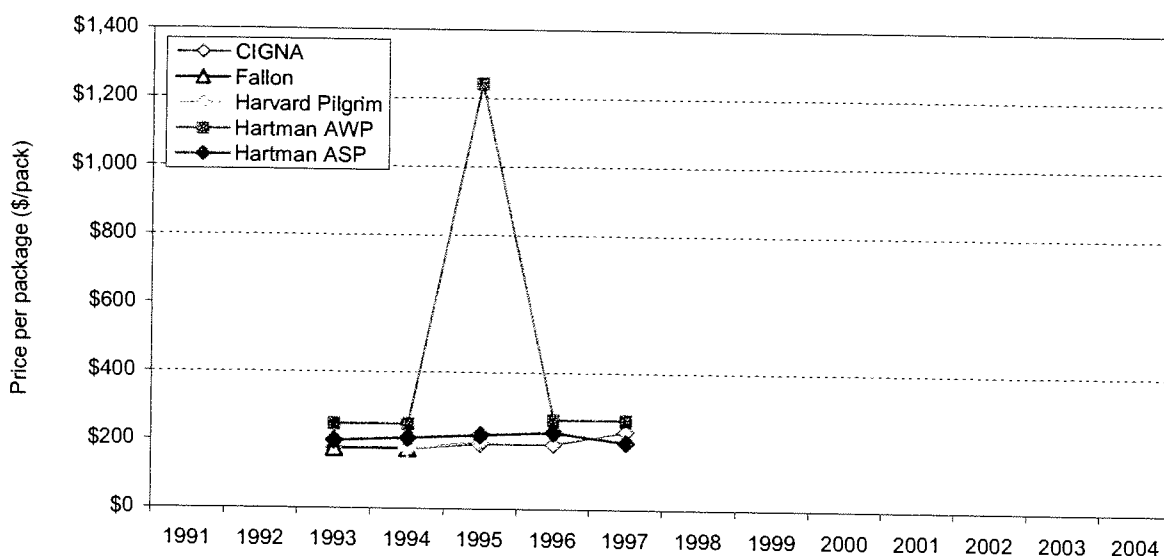
[282]   Dr. Hartman's AWP of $1,244.40 in 1995 appears to be incorrect. From January 1, 1995 until March 1, 1995, the AWP published in Medi-Span is $248.88. Effective March 1, 1995 and continuing through the end of the year, the AWP published in Medi-Span is $262.57. See Medi-Span Comprehensive Price History File.

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Figure 23: Intron (NDC 00085118402)

Figure 24: Perphenazine (NDC 59930160501)

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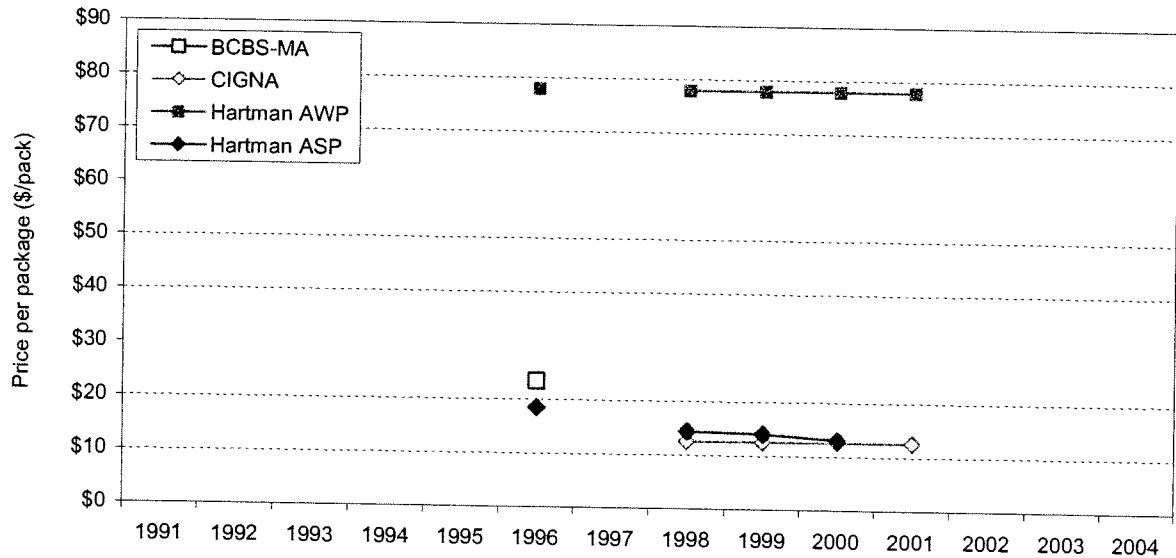
Figure 25: Proventil (NDC 00085020802)
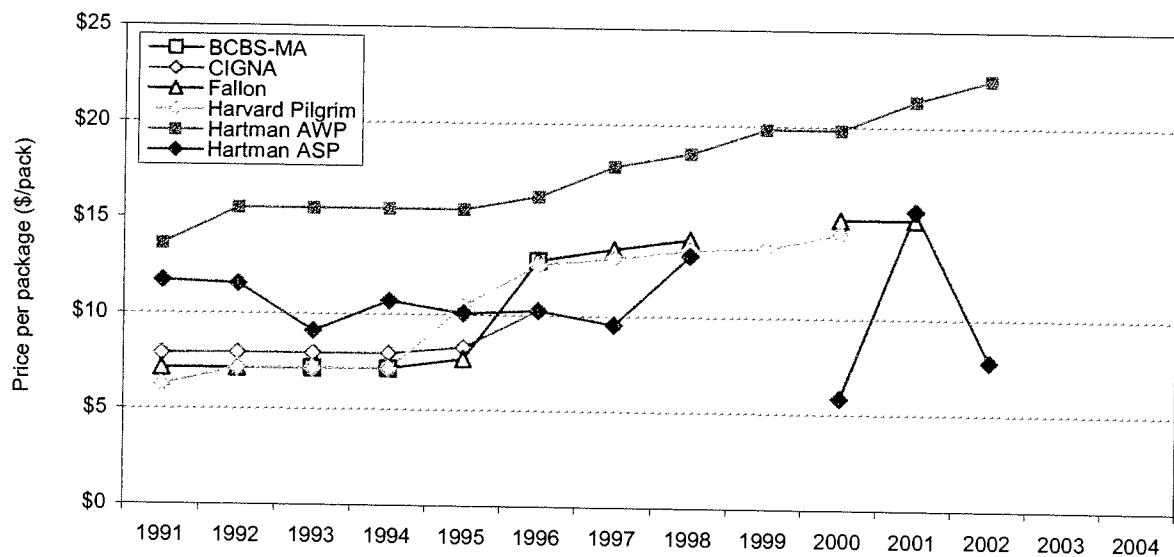
Figure 26: Proventil (NDC 00085020901)
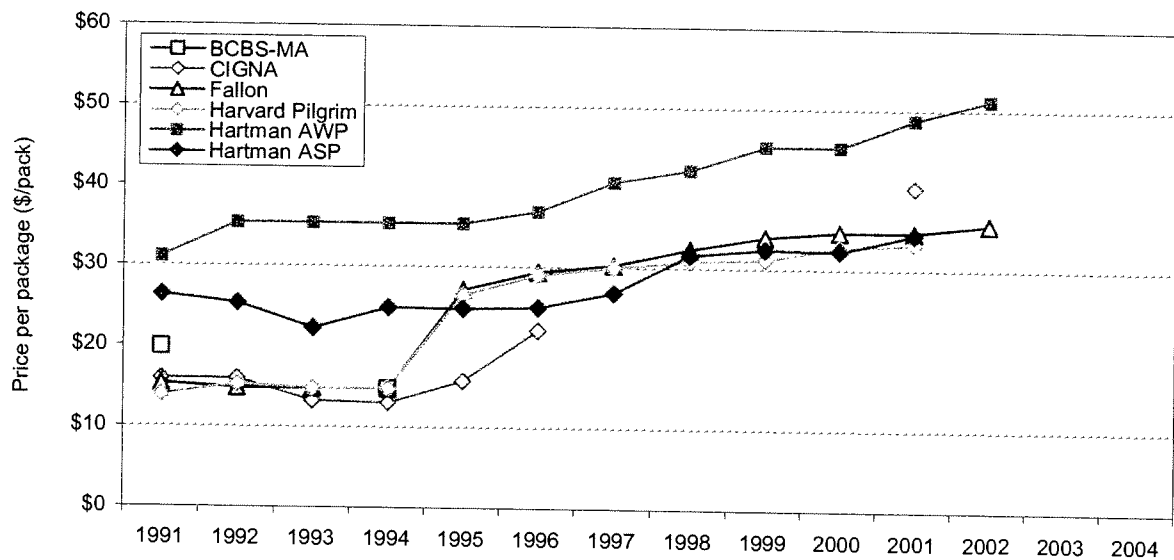
Appendix C: Adjustments for purported damages, by manufacturer and drug

Table 16: Adjustments for purported damages to Classes 1 and 2 for AstraZeneca drugs

Expectation applied as yardstick	Drug	Dr. Hartman's purported damages	Reduction in damages	Percent reduction
30 percent yardstick	PULMICORT	$0	$0	N/A
	ZOLADEX	$40,534,207	$7,892,334	19%
	TOTAL	$40,534,207	$7,892,334	19%
Greater of 30 percent and the median yardsticks from 1992 and 1997 OIG reports	PULMICORT	$0	$0	N/A
	ZOLADEX	$40,534,207	$10,031,624	25%
	TOTAL	$40,534,207	$10,031,624	25%
Greater of 30 percent and the maximum yardsticks from 1992 and 1997 OIG reports	PULMICORT	$0	$0	N/A
	ZOLADEX	$40,534,207	$40,534,207	100%
	TOTAL	$40,534,207	$40,534,207	100%

Source: Dr. Hartman's damage calculation materials in support of his December 15, 2005 Declaration; 1992 and 1997 OIG reports.

Table 17: Adjustments for purported damages to Class 3 for AstraZeneca drugs

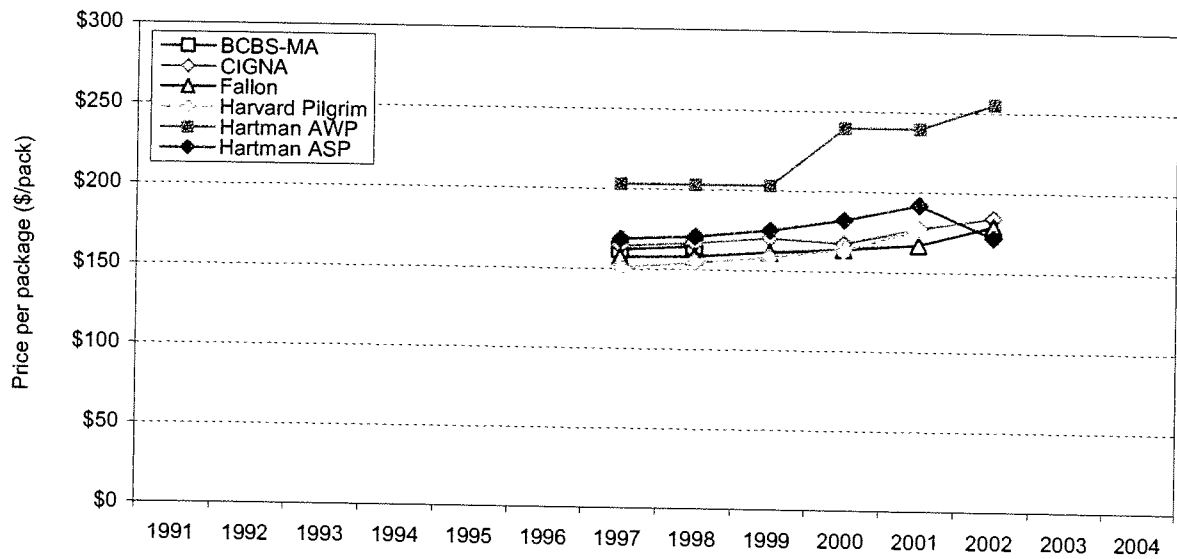| Expectation applied as yardstick	Drug	Dr. Hartman's purported damages	Reduction in damages	Percent reduction
Median markup from TPP direct purchases	PULMICORT	$0	$0	N/A
	ZOLADEX	$7,150,908	$478,432	7%
	TOTAL	$7,150,908	$478,432	7%
Maximum markup from TPP direct purchases	PULMICORT	$0	$0	N/A
	ZOLADEX	$7,150,908	$5,005,636	70%
	TOTAL	$7,150,908	$5,005,636	70%
Greater of 30 percent and the maximum yardsticks from 1992 and 1997 OIG reports	PULMICORT	$0	$0	N/A
	ZOLADEX	$7,150,908	$7,150,908	100%
	TOTAL	$7,150,908	$7,150,908	100%

Source: Dr. Hartman's damage calculation materials in support of his December 15, 2005 Declaration; 1992 and 1997 OIG reports; AstraZeneca chargeback data.

Table 18: Adjustments for purported damages to Classes 1 and 2 for Bristol-Myers Squibb drugs

Expectation applied as yardstick	Drug	Dr. Hartman's purported damages	Reduction in damages	Percent reduction
30 percent yardstick	BLENOXANE	$881,546	$355,828	40%
	CYTOXAN	$1,211,548	$242,005	20%
	ETOPOPHOS	$3,936	$3,300	84%
	PARAPLATIN	$4,477,769	$3,451,153	77%
	RUBEX	$127,636	$21,574	17%
	TAXOL	$2,691,119	$1,622,654	60%
	TEQUIN	$0	$0	N/A
	VEPESID	$3,143,939	$690,195	22%
	TOTAL	$12,537,493	$6,386,709	51%
Greater of 30 percent and the median yardsticks from 1992 and 1997 OIG reports	BLENOXANE	$881,546	$420,798	48%
	CYTOXAN	$1,211,548	$280,009	23%
	ETOPOPHOS	$3,936	$3,300	84%
	PARAPLATIN	$4,477,769	$4,428,249	99%
	RUBEX	$127,636	$23,835	19%
	TAXOL	$2,691,119	$1,904,564	71%
	TEQUIN	$0	$0	N/A
	VEPESID	$3,143,939	$729,675	23%
	TOTAL	$12,537,493	$7,790,430	62%
Greater of 30 percent and the maximum yardsticks from 1992 and 1997 OIG reports	BLENOXANE	$881,546	$881,546	100%
	CYTOXAN	$1,211,548	$1,211,131	100%
	ETOPOPHOS	$3,936	$3,936	100%
	PARAPLATIN	$4,477,769	$4,477,769	100%
	RUBEX	$127,636	$127,636	100%
	TAXOL	$2,691,119	$2,691,119	100%
	TEQUIN	$0	$0	N/A
	VEPESID	$3,143,939	$2,850,253	91%
	TOTAL	$12,537,493	$12,243,390	98%

Source: Dr. Hartman's damage calculation materials in support of his December 15, 2005 Declaration; 1992 and 1997 OIG reports.

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Table 19: Adjustments for purported damages to Class 3 for Bristol-Myers Squibb drugs

Expectation applied as yardstick	Drug	Dr. Hartman's purported damages	Reduction in damages	Percent reduction
Median markup from TPP direct purchases	BLENOXANE	$2,162	$1,513	70%
	CYTOXAN	$1,676,407	$131,580	8%
	ETOPOPHOS	$525	$223	42%
	PARAPLATIN	$889,731	$581,565	65%
	RUBEX	$0	$0	N/A
	TAXOL	$183,500	$128,450	70%
	TEQUIN	$0	$0	N/A
	VEPESID	$94,047	$54,035	57%
	TOTAL	$2,846,372	$897,366	32%
Maximum markup from TPP direct purchases	BLENOXANE	$2,162	$1,513	70%
	CYTOXAN	$1,676,407	$1,172,031	70%
	ETOPOPHOS	$525	$368	70%
	PARAPLATIN	$889,731	$622,812	70%
	RUBEX	$0	$0	N/A
	TAXOL	$183,500	$128,450	70%
	TEQUIN	$0	$0	N/A
	VEPESID	$94,047	$65,833	70%
	TOTAL	$2,846,372	$1,991,007	70%
Greater of 30 percent and the maximum yardsticks from 1992 and 1997 OIG reports	BLENOXANE	$2,162	$2,162	100%
	CYTOXAN	$1,676,407	$1,675,729	100%
	ETOPOPHOS	$525	$525	100%
	PARAPLATIN	$889,731	$889,731	100%
	RUBEX	$0	$0	N/A
	TAXOL	$183,500	$183,500	100%
	TEQUIN	$0	$0	N/A
	VEPESID	$94,047	$94,047	100%
	TOTAL	$2,846,372	$2,845,694	100%

Source: Dr. Hartman's damage calculation materials in support of his December 15, 2005 Declaration; 1992 and 1997 OIG reports; Bristol-Myers Squibb chargeback data.

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Table 20: Adjustments for purported damages to Classes 1 and 2 for GlaxoSmithKline drugs

Expectation applied as yardstick	Drug	Dr. Hartman's purported damages	Reduction in damages	Percent reduction
30 percent yardstick	ALKERAN	$75,441	$56,261	75%
	IMITREX	$0	$0	N/A
	KYTRIL	$2,118,114	$1,172,661	55%
	LANOXIN	$2,484	$1,606	65%
	MYLERAN	$0	$0	N/A
	NAVELBINE	$642,921	$582,439	91%
	RETROVIR	$0	$0	N/A
	VENTOLIN	$793,312	$506,178	64%
	ZOFRAN	$5,057,017	$2,036,956	40%
	ZOVIRAX	$6,596	$6,531	99%
	TOTAL	$8,695,885	$4,362,632	50%
Greater of 30 percent and the median yardsticks from 1992 and 1997 OIG reports	ALKERAN	$75,441	$70,885	94%
	IMITREX	$0	$0	N/A
	KYTRIL	$2,118,114	$1,345,529	64%
	LANOXIN	$2,484	$1,932	78%
	MYLERAN	$0	$0	N/A
	NAVELBINE	$642,921	$638,331	99%
	RETROVIR	$0	$0	N/A
	VENTOLIN	$793,312	$506,178	64%
	ZOFRAN	$5,057,017	$2,503,466	50%
	ZOVIRAX	$6,596	$6,561	99%
	TOTAL	$8,695,885	$5,072,882	58%
Greater of 30 percent and the maximum yardsticks from 1992 and 1997 OIG reports	ALKERAN	$75,441	$75,441	100%
	IMITREX	$0	$0	N/A
	KYTRIL	$2,118,114	$2,118,114	100%
	LANOXIN	$2,484	$2,484	100%
	MYLERAN	$0	$0	N/A
	NAVELBINE	$642,921	$642,921	100%
	RETROVIR	$0	$0	N/A
	VENTOLIN	$793,312	$787,754	99%
	ZOFRAN	$5,057,017	$5,057,017	100%
	ZOVIRAX	$6,596	$6,596	100%
	TOTAL	$8,695,885	$8,690,327	100%

Source: Dr. Hartman's damage calculation materials in support of his December 15, 2005 Declaration; 1992 and 1997 OIG reports.

Table 21: Adjustments for purported damages to Class 3 for GlaxoSmithKline drugs

Expectation applied as yardstick	Drug	Dr. Hartman's purported damages	Reduction in damages	Percent reduction
Median markup from TPP direct purchases	ALKERAN	$918	$457	50%
	IMITREX	$0	$0	N/A
	KYTRIL	$2,723,450	$780,805	29%
	LANOXIN	$0	$0	N/A
	MYLERAN	$0	$0	N/A
	NAVELBINE	$174,384	$117,990	68%
	RETROVIR	$0	$0	N/A
	VENTOLIN	$1,528	$23	2%
	ZOFRAN	$6,863,036	$1,195,094	17%
	ZOVIRAX	$1,544	$1,081	70%
	TOTAL	$9,764,860	$2,095,450	21%
Maximum markup from TPP direct purchases	ALKERAN	$918	$644	70%
	IMITREX	$0	$0	N/A
	KYTRIL	$2,723,450	$1,906,415	70%
	LANOXIN	$0	$0	N/A
	MYLERAN	$0	$0	N/A
	NAVELBINE	$174,384	$122,068	70%
	RETROVIR	$0	$0	N/A
	VENTOLIN	$1,528	$366	24%
	ZOFRAN	$6,863,036	$4,804,125	70%
	ZOVIRAX	$1,544	$1,081	70%
	TOTAL	$9,764,860	$6,834,699	70%
Greater of 30 percent and the maximum yardsticks from 1992 and 1997 OIG reports	ALKERAN	$918	$918	100%
	IMITREX	$0	$0	N/A
	KYTRIL	$2,723,450	$2,723,450	100%
	LANOXIN	$0	$0	N/A
	MYLERAN	$0	$0	N/A
	NAVELBINE	$174,384	$174,384	100%
	RETROVIR	$0	$0	N/A
	VENTOLIN	$1,528	$0	N/A
	ZOFRAN	$6,863,036	$6,863,036	100%
	ZOVIRAX	$1,544	$1,544	100%
	TOTAL	$9,764,860	$9,763,332	100%

Source: Dr. Hartman's damage calculation materials in support of his December 15, 2005 Declaration; 1992 and 1997 OIG reports; GlaxoSmithKline chargeback data.

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Table 22: Adjustments for purported damages to Classes 1 and 2 for Johnson & Johnson drugs

Expectation applied as yardstick	Drug	Dr. Hartman's purported damages	Reduction in damages	Percent reduction
30 percent yardstick	PROCRIT	$20,048,373	$17,398,189	87%
	REMICADE	$21,792,576	$18,555,712	85%
	TOTAL	$41,840,949	$35,953,901	86%
Greater of 30 percent and the median yardsticks from 1992 and 1997 OIG reports	PROCRIT	$20,048,373	$19,639,923	98%
	REMICADE	$21,792,576	$21,792,576	100%
	TOTAL	$41,840,949	$41,432,499	99%
Greater of 30 percent and the maximum yardsticks from 1992 and 1997 OIG reports	PROCRIT	$20,048,373	$20,048,373	100%
	REMICADE	$21,792,576	$21,792,576	100%
	TOTAL	$41,840,949	$41,840,949	100%

Source: Dr. Hartman's damage calculation materials in support of his December 15, 2005 Declaration; 1992 and 1997 OIG reports.

Table 23: Adjustments for purported damages to Class 3 for Johnson & Johnson drugs

Expectation applied as yardstick	Drug	Dr. Hartman's purported damages	Reduction in damages	Percent reduction
Median markup from TPP direct purchases	PROCRIT	$1,551,304	$985,354	64%
	REMICADE	$2,810,177	$1,967,124	70%
	TOTAL	$4,361,481	$2,952,478	68%
Maximum markup from TPP direct purchases	PROCRIT	$1,551,304	$1,085,780	70%
	REMICADE	$2,810,177	$1,967,124	70%
	TOTAL	$4,361,481	$3,052,904	70%
Greater of 30 percent and the maximum yardsticks from 1992 and 1997 OIG reports	PROCRIT	$1,551,304	$1,551,304	100%
	REMICADE	$2,810,177	$2,810,177	100%
	TOTAL	$4,361,481	$4,361,481	100%

Source: Dr. Hartman's damage calculation materials in support of his December 15, 2005 Declaration; 1992 and 1997 OIG reports; Johnson & Johnson chargeback data.

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Table 24: Adjustments for purported damages to Classes 1 and 2 for Schering-Plough drugs

Expectation applied as yardstick	Drug	Dr. Hartman's purported damages	Reduction in damages	Percent reduction
30 percent yardstick	ALBUTEROL	$40,541,206	$2,640,413	7%
	INTRON	$330,318	$229,900	70%
	PERPHENAZINE	$498,331	$36,835	7%
	PROVENTIL	$2,084,151	$1,602,518	77%
	TEMODAR	$78,392	$59,191	76%
	TOTAL	$43,532,398	$4,568,857	10%
Greater of 30 percent and the median yardsticks from 1992 and 1997 OIG reports	ALBUTEROL	$40,541,206	$3,136,147	8%
	INTRON	$330,318	$252,976	77%
	PERPHENAZINE	$498,331	$41,684	8%
	PROVENTIL	$2,084,151	$1,602,852	77%
	TEMODAR	$78,392	$71,601	91%
	TOTAL	$43,532,398	$5,105,260	12%
Greater of 30 percent and the maximum yardsticks from 1992 and 1997 OIG reports	ALBUTEROL	$40,541,206	$40,189,581	99%
	INTRON	$330,318	$314,066	95%
	PERPHENAZINE	$498,331	$498,331	100%
	PROVENTIL	$2,084,151	$1,943,050	93%
	TEMODAR	$78,392	$78,392	100%
	TOTAL	$43,532,398	$43,023,420	99%

Source: Dr. Hartman's damage calculation materials in support of his December 15, 2005 Declaration; 1992 and 1997 OIG reports.

Table 25: Adjustments for purported damages to Class 3 for Schering-Plough drugs

Expectation applied as yardstick	Drug	Dr. Hartman's purported damages	Reduction in damages	Percent reduction
Median markup from TPP direct purchases	ALBUTEROL	$0	N/A	N/A
	INTRON	$815,399	$212,655	26%
	PERPHENAZINE	$0	N/A	N/A
	PROVENTIL	$45,928	$1,324	3%
	TEMODAR	$0	N/A	N/A
	TOTAL	$861,327	$213,979	25%
Maximum markup from TPP direct purchases	ALBUTEROL	$0	N/A	N/A
	INTRON	$815,399	$379,752	47%
	PERPHENAZINE	$0	N/A	N/A
	PROVENTIL	$45,928	$11,023	24%
	TEMODAR	$0	N/A	N/A
	TOTAL	$861,327	$390,775	45%
Greater of 30 percent and the maximum yardsticks from 1992 and 1997 OIG reports	ALBUTEROL	$0	N/A	N/A
	INTRON	$815,399	$698,233	86%
	PERPHENAZINE	$0	N/A	N/A
	PROVENTIL	$45,928	N/A	N/A
	TEMODAR	$0	N/A	N/A
	TOTAL	$861,327	$698,233	81%

Source: Dr. Hartman's damage calculation materials in support of his December 15, 2005 Declaration; 1992 and 1997 OIG reports; Schering-Plough chargeback data.

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Appendix D: Description of electronic data

Electronic data sources

Manufacturer sales data

AstraZeneca

Data tables

- Direct sales

    - cnt_mgt_zoladex_direct_sales

- Chargeback sales

    - cntmgt_pulmicortresp_indirect_sales

    - cntmgt_zoladex_indirect_sales

- Customer information

    - AZ_Sales_Based_Customers.csv—produced by Dr. Hartman on February 3, 2006

Drugs included

- Pulmicort respules, Zoladex —only NDCs considered by Dr. Hartman are included

Fields for identifying products

- Direct: ndc_no

- Chargeback: product_ndc

Time coverage

- Direct: 1991–2002

- Chargeback: 1991–2004

Relevant date field

- Direct: invoice_date

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- Chargeback: invoice_date

Quantity fields

- Direct: qty_pkgs_invoiced

- Chargeback: no_of_packages

Fields used to calculate weighted unit contract prices paid by Massachusetts TPPs

- Chargeback: net_sales / no_of_packages

Price fields used for sales at list analysis

- Unit price in direct sales data: invoice_amount / no_of_packages

- Wholesale price in chargeback data: contract_pkg_price + (charge_back_amount / no_of_packages)

- Contract price in chargeback data: contract_pkg_price

Fields for identifying Massachusetts TPPs

- Chargeback: customer_name, contract_owner, customer_compass_id (to merge state information)

- Customer: customer_compass_id, state

Fields for identifying wholesalers in direct sales data for sales at list analysis

- customer_mkt_segment

Fields for removing duplicate transactions

- Direct: sales_indicator

Bristol-Myers Squibb

Data tables

- Direct sales

  - Direct.txt

- Chargeback sales

  - Indirect.txt

- OTN.txt

- Wholesale list price ("WLP") information

  - PricingRevised1.xls

Drugs included

- Blenoxane, Cytoxan, Paraplatin, Taxol, Vepesid —only NDCs considered by Dr. Hartman are included

Fields for identifying products

- Direct: ndc

- Chargeback: chbk-ndc-prod-code

Time coverage

- Direct: 1993–2002

- Chargeback: 1993–2002

Relevant date field

- Direct: invdate

- Chargeback: chbk_inv_date

Fields used to calculate weighted unit contract prices paid by Massachusetts TPPs

- Chargeback—Indirect.txt: (chbk-adj-contr-prc * chbk-adj-prod-qty) / sum(chbk-adj-prod-qty)

Price fields used for sales at list analysis

- Unit price in direct sales data: unit price

- Wholesale price in chargeback data:

  - Indirect.txt—chbk-adj-ws-prc

  - OTN.txt—WLP merged on by day from PricingRevised1.xls

- Contract price in chargeback data:

  - Indirect.txt—chbk-adj-contr-prc

- OTN.txt—unit price

Fields for identifying Massachusetts TPPs

- Chargeback: custname, ownername and custst

Fields for identifying wholesalers in direct sales data for sales at list analysis

- ccc

GlaxoSmithKline

Data tables

- Chargeback sales

  - ORS—cn_sales_v

  - IMHC—tcbline

- Customer information

  - ORS—cn_bu_vl

  - IMHC—trpcustmst

Drugs included

- Imitrex, Kytril, Navelbine, Ventolin, Zofran—only NDCs considered by Dr. Hartman are included

Fields for identifying products

- Chargeback: ORS—nwda_ndc11_no

- Chargeback IMHC—prod_nmbr

Time coverage

- Chargeback: 1997–2001

Relevant date field

- Chargeback: ORS—invc_dt

- Chargeback IMHC—whsle_invc_ship_dt

Fields for calculating sales quantities

- Chargeback: ORS—pkg_unit_qty

- Chargeback IMHC—prod_qty

Fields used to calculate weighted unit contract prices paid by Massachusetts TPPs

- Chargeback: ORS—contr_sls_amt / pkg_unit_qty

- Chargeback IMHC—(cont_prod_prc * prod_qty) / sum(prod_qty)

Fields for identifying Massachusetts TPPs

- Chargeback: ORS—bu_id, bu_nm, bu_std_nm, dflt_st_cd

- Chargeback IMHC—cust_nmbr, cust_name, owner_cust_name, hin_name and cust_state

Fields for identifying entities excluded by Dr. Hartman

- Chargeback IMHC—tc and tc_desc

Johnson & Johnson

Data tables

- Direct sales

  - daf1994_p

  - daf1995_p

  - daf1996_p

  - daf1997_p

  - daf1998_p

  - daf1999_p

  - daf2000_p

  - daf2001_p

  - daf2002_p

  - daf_data_2003

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- Chargeback sales

  - Used for calculation of dollars and prices paid by Massachusetts TPPs

    - imhc_jan_obi_p

  - Additional tables for sales at list analysis

    - imhc_missing_days_send_11112004

    - obi_1999_p

    - obi_2000_p

    - obi_2001_p

    - obi_2002p

    - obi_2003_0306

    - supplemental_cbks

    - dmcr_chargeback_p

    - chargebacks 2003 for awp

- Wholesale list price information

  - 2005_11.30_Procrit-Remicade_FDB.Pricing.xls

Drugs included

- Procrit and Remicade—only NDCs considered by Dr. Hartman are included

Fields for identifying products

- Direct: sap_prod

- Chargeback: imhc_jan_obi_p, obi data, supplemental_cbks—prod_ndc

- Chargeback: dmcr_chargeback_p—prod_id

- Chargeback: imhc_missing_days_send_11112004—NDC-11

- Chargeback: chargebacks 2003 for awp—NDC11

Time coverage

- Direct: 1991–2003

- Chargeback: 1993–2003

Relevant date field

- Direct: invoice-date

- Chargeback: obi data, supplemental_cbks— chargeback_process_date

- Chargeback: imhc_jan_obi_p, imhc_missing_days_send_11112004—cbk_process_date

- Chargeback: dmcr_chargeback_p—cbk_invoice_dt

- Chargeback: chargebacks 2003 for awp— invoice_dt

Fields for calculating sales quantities

- Direct: sap-qty (sap-qty is multiplied by negative 1 when sap-sign is "-")

- Chargeback: obi data, supplemental_cbks—units

- Chargeback: imhc_jan_obi_p, imhc_missing_days_send_11112004—cbk_prod_qty

- Chargeback: dmcr_chargeback_p—packages

- Chargeback: chargebacks 2003 for awp—units

Fields used to calculate weighted unit contract prices paid by Massachusetts TPPs

- Chargeback: (contract_prod_price* cbk_prod_qty) / sum(cbk_prod_qty)

Price fields used for sales at list analysis

- Unit price in direct sales data: sap-price

- Wholesale price in chargeback data:

  - Chargeback: Procrit—obi data, imhc_jan_obi_p, imhc_missing_days_send_11112004, supplemental_cbks—list_price

  - Chargeback: Remicade—dmcr_chargeback_p—cbk_wac

  - Chargeback: Remicade—chargebacks 2003 for awp—unit_price

- Contract price in chargeback data:

  - Chargeback: Procrit—obi data, supplemental_cbks—contract_price

- Chargeback: Procrit—imhc_jan_obi_p, imhc_missing_days_send_11112004—contract_prod_price

- Chargeback: Remicade—dmcr_chargeback_p—contract_price

- Chargeback: Remicade—chargebacks 2003 for awp—discount_price

Fields for identifying Massachusetts TPPs

- Chargeback: cust_name and cust_state

Fields for identifying wholesalers in direct sales data for sales at list analysis

- Direct: sap_cust and sap-cname

Schering-Plough

Data tables

- Chargeback sales

  - schering_chargeback_1991_1994

  - schering_chargeback_1995_1998

  - schering_chargeback_1999_2001

  - schering_chargeback_2002_2004

Drugs included

- Albuterol, Intron, Perphenazine, Proventil, Temodar—only NDCs considered by Dr. Hartman are included

Fields for identifying products

- Chargeback: ndc_no

Time coverage

- Chargeback: 1991–2004

Relevant date field

- Chargeback: invoice_date

Fields for calculating sales quantities

- Chargeback: quantity

Fields used to calculate weighted unit contract prices paid by Massachusetts TPPs

- Chargeback: extended_amount / quantity

Fields for identifying Massachusetts TPPs

- Chargeback: customer_name, buying_group_name and customer_state

Payor claim data

BCBS Massachusetts

Data table

- BCBSMA data w out 2 unions (appears in AWP Track 1 for OSC redacted.mdb)

Included codes and time coverage

- Data are restricted to years and drugs in Table 4 of Dr. Hartman's December 15, 2005 Declaration

Relevant date field

- serv-date

Units field

- number_services

Allowed amount field

- allowed_amt

Charged amount field

- charge_amt

Field for identifying drug

- proc-code

BCBS Kansas City

Data table

- awpmed.dat (extracted from awpmed.exe)

Included codes and time coverage

- Data are restricted to years and drugs in Table 4 of Dr. Hartman's December 15, 2005 Declaration

Relevant date field

- service_date

Units field

- units

Allowed amount field

- allowed_charge

Charged amount field

- provider_charge

Field for identifying drug

- claim_line_procedure_code

Field for identifying out-of-network providers

- provider_network_status

Field for removing Medicare-related claims

- cob_type

CIGNA

Data tables

- AWP.CLM2002

- AWP.CLM2003

- AWP.CLM2004

- AWP.PPO2002

- AWP.PPO2003

- AWP.PPO2004

- WP.CLMARCVD

- WP.PPOARCVD

Included codes and time coverage

- Data are restricted to years and drugs in Table 4 of Dr. Hartman's December 15, 2005 Declaration

Relevant date field

- svc_dt

Units field

- unit_qty

Allowed amount field

- elgbl_chrg_amt

Charged amount field

- chrg_amt

Field for identifying drug

- proc_cd

Field for identifying out-of-network providers

- phys-network-status

Field for removing Medicare-related claims

- medcr_ind

Health Net

Data table

- ABS_Injectibles_Encrypted_1996_2004

Supporting documentation, including variable decode information

- Injectibles_Action_Code_Lookup_Values.pdf

- Injectibles_Encrypted_Table_Data_Layouts.pdf

- Injectibles_RMC_Code_Lookup_Values.pdf

Included codes

- J9000 (doxorubicin HCL 10 mg)

- 90780 (IV infusion therapy, 1 hr)

Time coverage

- 1996–2004

Units field

- total_units

Relevant date field

- thru_date

Fields for calculating unit price

- allowed_amt / total_units

Field for identifying drug and service

- proc_code

Fields for removing duplicate transactions

- icn

- icn_line_no

Fields for removing Medicare-related claims

- rmc_code

Fields for removing denied claims

- action_code

Remove out-of-network claims

- contr_ind

Oxford Health Plans

Data table

- SIU_Jcode_Report.dbf

Supporting documentation, including variable decode information

- adjustment codes.doc

- place of service codes.doc

Included codes and time coverage

- Data are restricted to years and drugs in Table 4 of Dr. Hartman's December 15, 2005 Declaration

Relevant date field

- dosdte

Fields for calculating unit price

- allowamt / proc_qty

Charged amount field

- reqamt

Field for identifying drug

- proccode

Field for identifying place of service

- placecod

Field for removing Medicare-related claims

- adjcode

Field for identifying provider name

- prvlname

Field for identifying unique providers

- prvcode

Publicly available data

AIS's Directory of Health Plans: 2004, MCOs table

- This file contains the number of enrollees by managed care organization and state

Healthcare Common Procedure Coding System ("HCPCS") Drug Pricing Background File

- This file contains J Code to NDC translations and also provides information on the base dosage for each J Code. Base dosage information is used to convert the per-pack AWP to an AWP expressed in terms of units consistent with HCPCS.

Medi-Span Comprehensive Price History File

- This file contains all active and inactive drug price histories, including AWP and WAC, that are maintained in Medi-Span's internal drug file

Electronic data procedures

Section IV.1.: Direct purchases by Massachusetts TPPs

- Create purchaser table

  - Identify relevant purchasing entities using customer name, owner name, and state fields present in the manufacturers' data

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- Identify purchases by Massachusetts TPPs and their related entities[283]

- For payors other than CIGNA, a national health plan, I restrict my analysis to purchases in Connecticut, New Hampshire, New Jersey, New York, Massachusetts, Rhode Island, and Vermont

- Table 26 below lists the customer/contracting entities appearing in the manufacturers' chargeback data that I identify as being related to a Massachusetts TPP

- Create sales table

  - Pull sales data from manufacturers' chargeback tables as specified above

    - Limit selection to NDCs included in Dr. Hartman's damage analysis

- Merge sales table and purchaser table

  - Keep only sales data for relevant purchasing entities

- Merge manufacturers' data with Dr. Hartman's AWP and ASP data

- Sum purchases by Massachusetts TPP and manufacturer

- Sum purchases by Massachusetts TPP and year

- For price graphs, calculate quantity-weighted purchase prices by year and Massachusetts TPP

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[283] The following table details the entities I include in my analysis.

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Table 26: Purchasing entities related to top Massachusetts TPPs[284]

TPP	Purchaser name from chargeback data	Relationship to TPP
BCBS-MA	HMO Blue	Health plan offered by BCBS-MA starting in 1992[285]
BCBS-MA	Medical East	Staff model HMO owned by BCBS-MA from the late 1980's through 1997[286]
BCBS-MA	Medical West	Staff model HMO owned by BCBS-MA from the late 1980's through 1997[287]
BCBS-MA	Bay State Health Care, Inc	Merged with BCBS-MA in 1992[288]
CIGNA	CIGNA Pharmacy	Offered as part of CIGNA's health plan[289]
CIGNA	Connecticut General Life Insurance Company (CG)	Merged with INA Healthplan to become CIGNA in 1982[290]
CIGNA	Insurance Company of North America (INA Healthplan)	Merged with CG to become CIGNA in 1982[291]
CIGNA	EQUICOR	Employee benefit plan purchased by CIGNA in 1990[292]
CIGNA	Lovelace Health Systems, INC (Lovelace)	Integrated healthcare system which was a subsidiary of CIGNA from 1991–2003[293]

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[284] AIS Directory of Health Plans, 2004, MCOs table.

[285] http://www.bluecrossma.com/common/en_US/aboutUsIndex.jsp. See History section of this link for discussion of HMO Blue's beginnings in 1992. Also note that HMO Blue is a current plan offering of BCBS-MA. See http://www.bluecrossma.com/common/en_US/healthPlansIndex.jsp?levelOneDotFive Category=HMO&levelTwoCategory=HMO+Blue&targetTemplate=titleBodyAddLvl.jsp.

[286] See Mulrey deposition, pp. 12–13, 17. Also see http://www.bluecrossma.com/common/en_US/aboutUsIndex.jsp?repId= Repositories.PressReleases.2001PressReleases.pressRelease04052001.xml&levelTwoCategory=News+%2 8with+Archives%29&isLevelThreeSelected=true&targetTemplate=pressReleaseDetail.jsp&iphl=medicall: medical:east.

[287] See Mulrey deposition, pp. 12–13, 17. Also see http://www.bluecrossma.com/common/en_US/aboutUsIndex.jsp?repId=Repositories. PressReleases.2001PressReleases.pressRelease04052001.xml&levelTwoCategory=News+%28with+Archi ves%29&isLevelThreeSelected=true&targetTemplate=pressReleaseDetail.jsp&iphl=medicall:medical:east.

[288] Merged with BCBSMA in 1992. See http://caselaw.lp.findlaw.com/cgi-bin/getcase.pl?court=1st&navby=case&no=012586. Also see http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=101 33054&query_hl=2&itool=pubmed_docsum.

[289] http://www.cigna.com/health/consumer/service/pharmacy_claim.html.

[290] In 1982 Connecticut General Life Insurance Company and the Insurance Company of North America, two health care insurance carriers, merged to form CIGNA. See http://www.cigna.com/general/about/history.html.

[291] http://www.cigna.com/general/about/history.html.

[292] http://www.cigna.com/general/about/history.html.

TPP	Purchaser name from chargeback data	Relationship to TPP
CIGNA	RxPrime	PBM managed by CIGNA from 1992 through 2000[294]
CIGNA	Tel-Drug	Mail order pharmaceutical company purchased to merge with RxPrime from 1993–2000[295]
CIGNA	Healthsource	Health care company purchased by CIGNA in 1997[296]
Fallon Community Health Plan (FCHP)	Fallon Clinic	Founded the Fallon Clinic Foundation which managed FCHP until 2004[297]
Fallon Community Health Plan (FCHP)	Fallon Central Pharmacy (FCP)	Main pharmacy for the Fallon Clinic until 2002[298]
Harvard Pilgrim Health Care (HPHC)	Harvard Community Health Plan (HCHP)	Staff Model HMO that merged with HPHC in 1994. Owner of Harvard Vanguard through 1997.[299]

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[293] CIGNA acquired 100 percent ownership of Lovelace in 1991 and sold the subsidiary to Ardent Health in 2003. See http://www.cigna.com/general/about/investor/release/10k20021231.html and http://www.ardenthealth.com/CustomPage.asp?PageName=Lovelace. Also see http://www.lovelacesandia.com/CustomPage.asp?guidCustomContentID=A89B6170-7BC2-4F3D-97A5-41F9BA70E1D5.

[294] http://www.cigna.com/general/about/history.html and http://www.equityleague.org/PDF/cigna_pharmacy_guide.pdf.

[295] http://www.cigna.com/general/about/history.html.

[296] http://www.cigna.com/general/about/history.html.

[297] Fallon Clinic is a healthcare provider organization, which runs medical centers, physician offices, ambulatory care centers, and other provider locations. See http://www.fchp.org/about/index.aspx and http://www.fchp.org/brokers/qa.aspx#Anchor246. Fallon Clinic founded The Fallon Clinic Foundation, a non-profit public charity, 1988. The Fallon Clinic Foundation governed Fallon Community Health Plan until 2004. See http://www.bizjournals.com/boston/stories/2005/01/03/daily50.html and http://www.fallonclinicfoundation.org/ourstory/ourstory.aspx. Each Fallon Clinic location can be called a Fallon Medical Center. For example, the clinic location in Auburn, MA can be called "Fallon Medical Center Auburn," as shown in http://www.fchp.org/SeniorPortal/Sales.aspx. Also see http://www.fallonclinic.com/internet/patients/index.aspx?PAGE=locations&LEVEL1=patients&LEVEL2=locations.

[298] http://www.fchp.org/brokers/resources/brokerEdge/BrokerEdgeFall02.pdf.

[299] Harvard Community Health Plan was a health insurance carrier, founded in 1969, that merged with Harvard Pilgrim Health Care in 1994 and took on the name Harvard Pilgrim. http://www.managedcaremag.com/archives/0002/0002.harvard.html and http://www.prospect.org/columns/kuttner/bk000109.html.

TPP	Purchaser name from chargeback data	Relationship to TPP
Harvard Pilgrim Health Care (HPHC)	Harvard Vanguard	Physician group, founded in 1969 by HCHP, spun off from HPHC in 1997[300]
Harvard Pilgrim Health Care (HPHC)	Multigroup	Regional New England HMO acquired by HCHP in 1986[301]
Harvard Pilgrim Health Care (HPHC)	Rhode Island Group Health (RIGH)	Staff model HMO acquired by HCHP in 1992, which closed in 1999[302]

Section IV.3.: Health Net's reimbursements for J9000 (doxorubicin HCL) and 90780 (IV infusion therapy, 1 hr)

- Restrict Health Net California reimbursement data to procedure code J9000 and 90780

- Limit data considered for analysis in the following manner:

  - Remove duplicate transactions using icn and icn_line_no fields

  - Remove Medicare-related claims using rmc_code field. The following values are removed:

    - 1M—CA-Medicare Supplement Indemnity Individual

    - 6—CA-Medicare Supplement

    - H—CA-Medicare HCFA Group

    - JM—CA-Medicare Options Plus (Med Supplemental PPO)

    - M—CA-Medicare Risk-Seniority Plus

    - N—CA-Medicare Risk-Seniority Plus: POS 2 Tier

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[300] http://www.bizjournals.com/boston/stories/1999/12/20/story6.html. Also see http://www.harvardvanguard.org/about/faq.asp. Also see http://www.managedcaremag.com/archives/0002/0002.harvard.html.

[301] Regional New England HMO acquired by Harvard Community Health Plan in 1986. http://www.managedcaremag.com/archives/0002/0002.harvard.html.

[302] http://findarticles.com/p/articles/mi_qa4100/is_200506/ai_n14715983. Also see http://www.managedcaremag.com/archives/0002/0002.harvard.html.

- • O—OR-Medicare Supplement

  - • S—CA-Medi-Cal Groups

  - • T—CA-Medicare Supplement (3-Tier POS)

  - • W—CA-Medicare Supplement (2-Tier POS)

- • Remove denied claims using action_code field

  - • Records with an action_code value of "D" are removed

- • Remove out-of-network claims using contr_ind field

  - • Records with a contr_ind value not equal to "Y" are removed

Section V.1.: Sales at list price

- • Prepare direct and chargeback data for analysis

  - • For AstraZeneca, to avoid duplication, exclude direct sales where sales_indicator is "A"

  - • For Johnson & Johnson, limit analysis to years of complete data in daf direct sales data—1995 through 2003. Due to missing chargeback sales, exclude the period September 1, 2002 through December 31, 2002 from the analysis.

- • Using direct sales data, sum dollar sales to wholesalers

  - • For AstraZeneca, wholesalers were identified where the customer_mkt_segment field is "WH"

  - • For Bristol-Myers Squibb, wholesalers were identified where the ccc field is "11"

  - • For Johnson & Johnson, wholesalers were identified manually based on customer names

  - • For Schering-Plough, wholesalers were identified where the customer_cot field is "111," "113," "119," "912," or "915"

- • Sum dollar sales at wholesale price in chargeback data. Sales were calculated as wholesale price multiplied by quantity.

- For Bristol-Myers Squibb's OTN data, the wholesale price was applied by day from the WLP data provided by Bristol-Myers Squibb

- Sales at list price are calculated as the sum of the following three components:

  - (1) On an annual basis, subtract dollar sales at wholesale price in chargeback data from dollar sales to wholesalers in direct sales data. Negative values are set to zero.

    - For Bristol-Myers Squibb, sales from OTN data were subtracted from sales to wholesalers only after April 2001. Prior to this time, sales through OTN were not recorded in the direct sales data.

  - (2) Identify direct sales to non-wholesalers transacted at list price. Prices in direct sales data were compared to list prices on a daily basis.

    - For AstraZeneca, list prices were obtained from Medi-Span

    - For Bristol-Myers Squibb, list prices were identified from WLP price file produced by Bristol-Myers Squibb

    - For Johnson & Johnson, list prices were identified from First DataBank data provided by Johnson & Johnson

    - For Schering-Plough, list prices were obtained from Medi-Span

  - (3) Identify chargeback sales transacted at list price. Contract prices in chargeback data were compared to list prices on a daily basis.

    - For AstraZeneca, list prices were obtained from Medi-Span

    - For Bristol-Myers Squibb, list prices were identified from WLP price file produced by Bristol-Myers Squibb

    - For Johnson & Johnson, list prices were identified from First DataBank data provided by Johnson & Johnson

    - For Schering-Plough, list prices were obtained from Medi-Span

- Total sales are calculated by summing:

  - Component (1) above

  - Total sales to non-wholesalers in the direct sales data

- Total sales in chargeback data

- Calculate percentage of total sales at list

Section V.4.: Reimbursements not based upon AWP

Non-hospital providers reimbursed at "unclear" amounts

- Identify the tax identification numbers associated with transactions Dr. Hartman deems "unclear"

- Using publicly available information (e.g., knowx.com), identify the entities corresponding to these tax identification numbers

- Based on entity name, determine whether providers are hospitals

- Where possible, entities were identified in the customer information accompanying the GlaxoSmithKline sales data. Customer codes for these entities were compared to those Dr. Hartman excludes from his damage calculations in order to determine whether the identified entities were excluded by Dr. Hartman.

"Unclear" reimbursements to non-hospital providers according to Dr. Hartman's methodology applied to Oxford Health data

- I apply Dr. Hartman's methodology to data from Oxford Health, in which hospital outpatient reimbursements, reimbursements to PBMs, and reimbursements in the Medicare context are explicitly identified and can be excluded

  - Include claims with the following values in the place of service field

    - 11—Office

    - 12—Home

    - 33—Custodial Care Facility

    - 65—End Stage Renal Disease

    - 4—Homeless Shelter

    - 81—Independent Lab

- - 32—Nursing Facility

  - 31—Skilled Nursing Facility

- Remove claims associated with the following values in the provider name field

  - "HOSP"

  - "MEDICAL CENTER"

  - "MEDICAL CTR"

  - "MED CTR"

  - "MED BUILDING"

  - "DEPARTMENT OF MEDICINE"

- Remove claims associated with the following values of the provider name field

  - "DIRECT SCRIPT"

  - "CAREMARK"

- Remove claims reimbursed in the Medicare context

  - Remove claims where adjustment code is A27—"Requested Amount if Medicare Approved"

- Remove providers that appear with less than 95 percent of claims as non-hospital claims. The Prvcode field was used to identify providers

- Reimbursements at the following percentages of AWP were not deemed to be "unclear"

  - Intron: 90, 91, 94, 95, 100, 103

  - Remicade: 90, 94, 95, 100

  - Taxol: 90, 95, 100

  - Zofran: 94, 95, 98, 100

  - Zoladex: 90, 94, 95, 97, 100